THE EFFICACY OF BOTULINUM TOXIN-A VERSUS METHYL PREDNISOLONE ACETATE INJECTION IN REDUCING PAIN AND IMPROVING FUNCTIONAL OUTCOME IN PLANTAR FASCIITIS

Dissertation submitted to

The Tamil Nadu Dr. MGR Medical University

In partial fulfilment of the regulations for the award of the degree of

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CHENNAI –600032

2017 - 2019

DECLARATION

I, **DR.GEETHA.T,** declare that, this dissertation entitled **"THE EFFICACY OF BOTULINUM TOXIN-A VERSUS METHYL PREDNISOLONE ACETATE INJECTION IN REDUCING PAIN AND IMPROVING FUNCTIONAL OUTCOME IN PLANTAR FASCIITIS"** is the original work done by me**, DR GEETHA T,Reg.No. 201729001** in the Government Institute of Rehabilitation Medicine, Madras Medical College, Chennai under the direct guidance and supervision of **Prof.Dr.C.Ramesh,** Government Institute of Rehabilitation Medicine, Madras Medical College, Chennai as guide and is submitted to the The Tamil Nadu Dr.M.G.R.Medical University, Chennai, in partial fulfilment of the board regulations for the award of the degree of **M.D.(Physical Medicine and Rehabilitation).**

DR GEETHA T

CERTIFICATE

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Dr. GEETHA .T

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CONTENTS

LIST OF ABBREVIATIONS

PF	-	Plantar Fasciitis
VAS	-	Visual Analog Scale
FAAM	-	Foot Ankle Ability Measure
BTX-A	-	Botulinum Toxin-A
ICD	-	International code for disease
ICF	-	International classification of functioning
USG	-	Ultrasonagram
MRI	-	Magnetic Resonace Imaging
NSAIDS	-	Non Steroidal Anti Inflammatory Drugs
ROM	-	Range of motion
PRP	-	Platelet rich plasma
FPI	-	Foot pressure index

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Introduction

INTRODUCTION

Background:

Heel pain is one of the most commonest complaints seen among foot disorders in PMR OPD.The main cause of this heel pain is mostly due to Plantar fasciitis.Plantar fasciitis occurs in about 2 million people every year in western countries[1]

Plantar fasciitis is prevalent both in atheletic and non atheletic population[2]. Plantar fasciitis leads to negative impact on foot specific and health related quality of life[3.] Though plantar fasciitis is self limiting disease,in some cases if not treated properly leads to chronic pain disease.

Plantar fascia acts as dynamic shock absorber and it also give support to the longitudinal arch of the foot[4.]Plantar fasciitis occurs due to repetitve trauma to plantar fascia leading to degenerative changes at its calcaneal origin leading to pain and dysfunction[5.]

The common age group involved in plantar fasciitis is between 45 to 64 yrs and more common in women.

As our day to day activities begins with standing,walking, if there is any heel pain ,it will lead to gait disturbances, and there by interfering the whole day activities and if not treated leading to significiant morbidity[6]

The predisposing factors for plantar fasciitis are increased weigh gain, foot deformity like pes cavus,pesplanus,tight tendo Achilles,those involved in long standing works,runners,limited ankle dorsiflexion,hamstring tightness,lower limb length discrepancy[7]

Usually patient will present with early morning heel pain with difficulty in walking and aggravated by weight bearing activities. Heel pain occurs mostly over medial calcaneal tuberosity, but may also present in posterior plantar heel, central arch, lateral heel.

Mostly patient with PF shows calcaneal spur in their x-ray but it is not concomitant with heel pain always. Thickness of plantar fasciitis is easily measured by ultrasonagraphy. Some previous studies shows that thickness of Plantar Fascia correlates with severity of pain.

The treatment approaches varies from medical management like NSAIDS, physical modalities like icing, ultrasound therapy, taping, phonophoresis, ionotophorosis, extracorporeal shock wave lithotripsy.

Exercise therapy like stretching exercise to plantar fascia, stretching exercise to tendoachilles, hamstrings, intrinsic foot muscle exercise, orthotic modification like night splints, foot wear modifications.

Interventions like corticosteroids,platelet rich plasma therapy, prolotherapy etc and if needed surgical management like resection of plantar fascia or any two combined treatments which are briefed in Review of literature section.

Corticosteroid injection is one of the treatment given most commonly in plantar fasciitis but complications of steroid like plantar fascia rupture, heel pad atrophy, infections can occur.

There is level B evidence that Botulinum toxin can be probably effective and recommended for Plantar fasciitis. Botulinum toxin-A is found to act on synaptosomal associated protein with the molecular mass of 25KDn(SNAP 25) which is located in the cell membrane.

This SNAP 25 present in sensory neurons acted upon by BTX producing anti-nociceptive effect[8].Botulinum Toxin also inhibits neurotransmitters like substance P,CGRP,glutamate and also has anti inflammatory action.

Need for this study:

As plantar fasciitis is a common condition and may become as chronic pain condition leading to significant functional disability, it can be treated with intervention if usual conservative management fails or to avoid unnecessary surgical complications.

So this study is proposed to find the efficacy of Botulinum Toxin-A versus the Methyl prednisolone acetate injection in reducing pain and improving functional outcome in patients with chronic plantar fasciitis in Government Institute of Rehabilitation Medicine hospital.

Aim & objectives

AIM & OBJECTIVES

"The efficacy of Botulinum Toxin-A versus Methyl Prednisolone Acetate injection in reducing pain and improving functional outcome in plantar fasciitis''- A Randomized Controlled Study.

Review of Literature

REVIEW OF LITERATURE

HISTORY:

Stiell in 1922 explained that painful heel appears to be a condition which is not efficiently treated because the exact cause is not known. Lupidus and Guidotti in 1961 also used the term painful heel as definite clinical cause for this not known[9]

RELEVANT ANATOMY[10]:

The deep fascia of the dorsum of the foot is thin where it is continuous proximally with the inferior extensor retinaculum. Over the lateral and posterior aspects of the foot, the deep fascia is continuous with the plantar fascia, the deep fascia of the sole.

The plantar fascia has thick central ,weaker medial and lateral parts which arises from medial tuberosity of calcaneus and then inserted into ball of foot.

The thick central part forms the plantar aponeurosis which are the longitudinally arranged bundles of dense fibrous connective tissue which encloses central plantar muscles and they form five slips which then became continuous with the fibrous flexor sheaths that are attached to toes.

The plantar fascia holds the parts of the foot together, protect the sole from injury and helps to support the longitudinal arches of the foot.

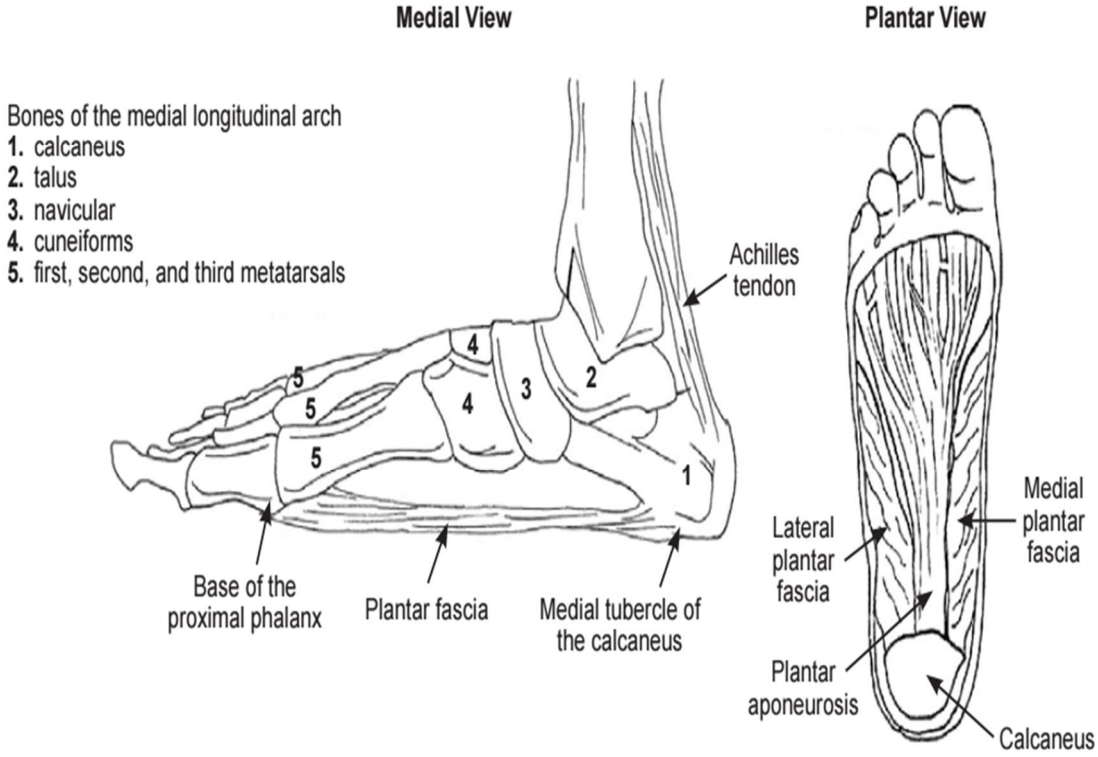

Fig 1:schematic diagram of plantar fascia[22]

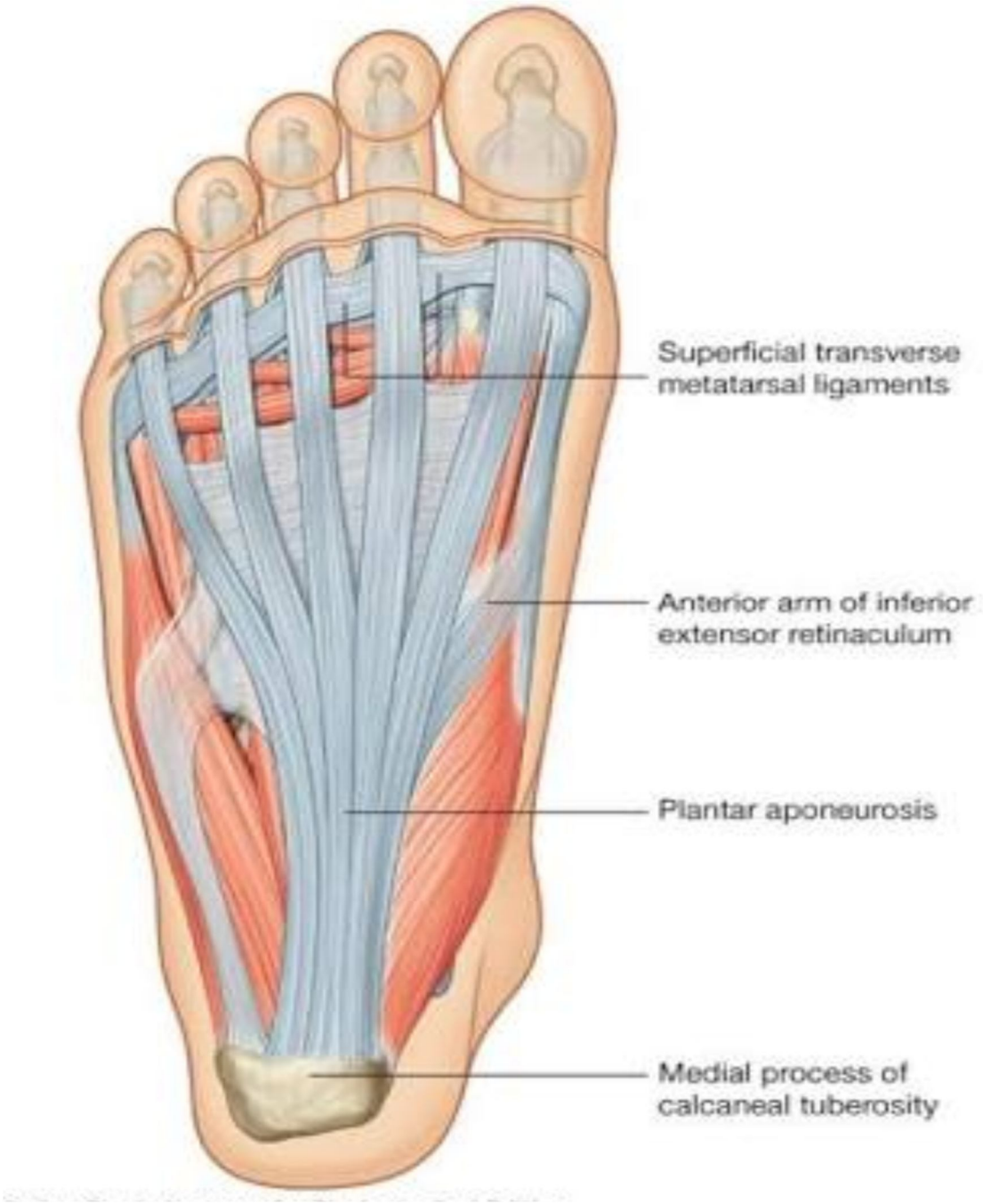

Fig 2- Anatomy of Plantar Fascia and its slips[11].

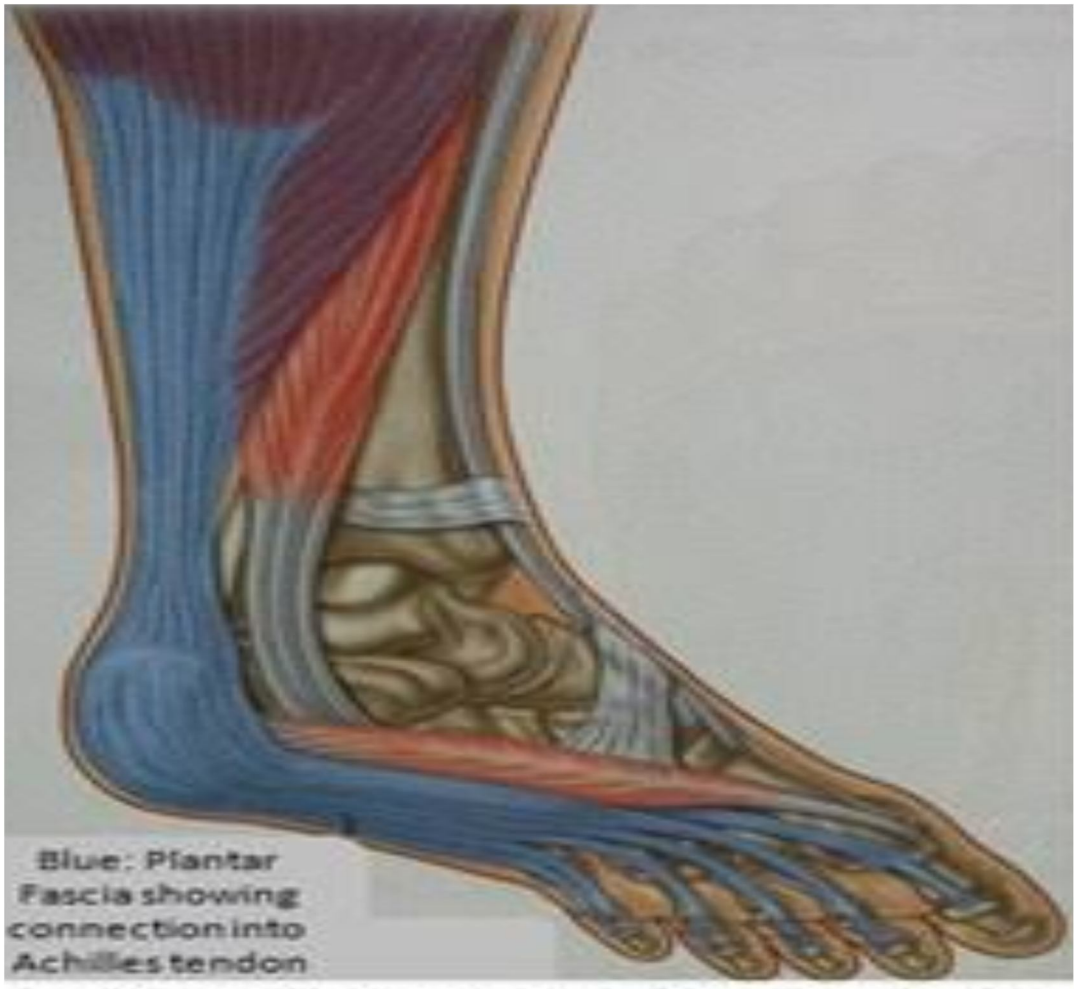

Fig 3 –Plantar fascia connection to tendoachilles[42].

The plantar aponeurosis arises from the calcaneus posteriorly and act like a superficial ligament. Distally, the longitudinal bundles of collagen fibres of the aponeurosis divide into five bands that became continuous with the fibrous digital sheaths that are covered by the flexor tendons and then they are attached to toes pass to the toes.

At the anterior end of the sole, inferior to the heads of the metatarsals, the aponeurosis is reinforced by transverse fibres forming the superficial transverse metatarsal ligament.

The medial compartment of sole is covered superficially by thinner medial plantar fascia which contains abductor hallucis, flexor hallucis longus and brevis, medial plantar nerve and vessels.

The central compartment of the sole is covered superficially by the dense plantar aponeurosis. It contains the flexor digitorum brevis, the tendon of the flexor hallucis longus and flexor digitorum longus, quadratus plantae and lumbricals, adductor hallucis. The lateral plantar nerve and vessels also located here.

The lateral compartment of sole is covered by thinner lateral plantar fascia and contains the abductor and flexor digiti minimi brevis[10].

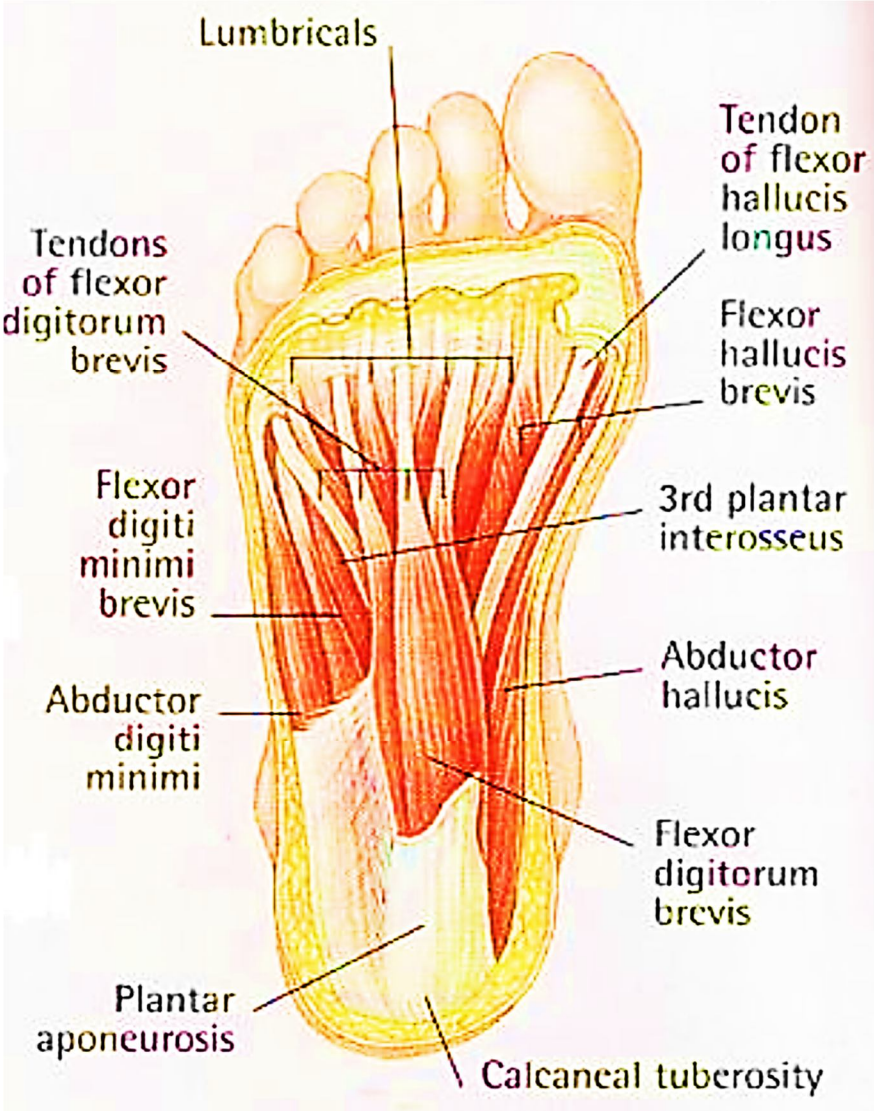

Fig 4 -Muscles invested by plantar fascia[43]

Arches of foot[10]:

If the feet were more rigid structures,each impact with the ground would generate extremely large forces of short duration that would be propagated through the skeletal system.Because the foot is composed of numerous bones connected by ligaments,it has considerable flexibility that allows it to deform with each ground contact,there by absorbing much of the shock.

The tarsal and metatarsal bone are arranged in longitudinal and transverse arches passively supported and actively restrained by flexible tendons that add to the weight bearing capabilities and resiliency of foot.Thus much smaller forces of longer duration are transmitted through the skeletal system.

The arches distribute weight over the foot,acting not only as shock absorbers but also as spring boards for propelling it during walking,running and jumping.The resilient arches add to the foot's ability to adapt to changes in surface contour.

The weight of the body is transmitted to the talus from the tibia.Then it is transmitted posteriorly to the calcaneus and anteriorly to the ball of the foot(the sesamoids of the 1^{st} metatarsal and the head of the 2^{nd} metatarsal), and that weight/pressure is shared laterally with the heads of the 3^{rd}-5^{th} metatarsals as necessary for balance and comfort.

Between these weight-bearing points are the relatively elastic arches of the foot, which become slightly flattened by body weight during standing. They normally resume their curvature when body weight is removed.

Passive factors involved in forming and maintaining the arches of the foot include the shape of the united bones (both arches, but especially the transverse arch) and four successive layers of fibrous tissue that bowstring the longitudinal arch (superficial to deep) ie plantar aponeurosis, long plantar ligament, plantar calcaneocuboid ligament, plantar calcaneonavicular ligament.

The plantar ligaments and the plantar aponeurosis bear the greatest stress and are most important in maintaining the arches of the foot[10].

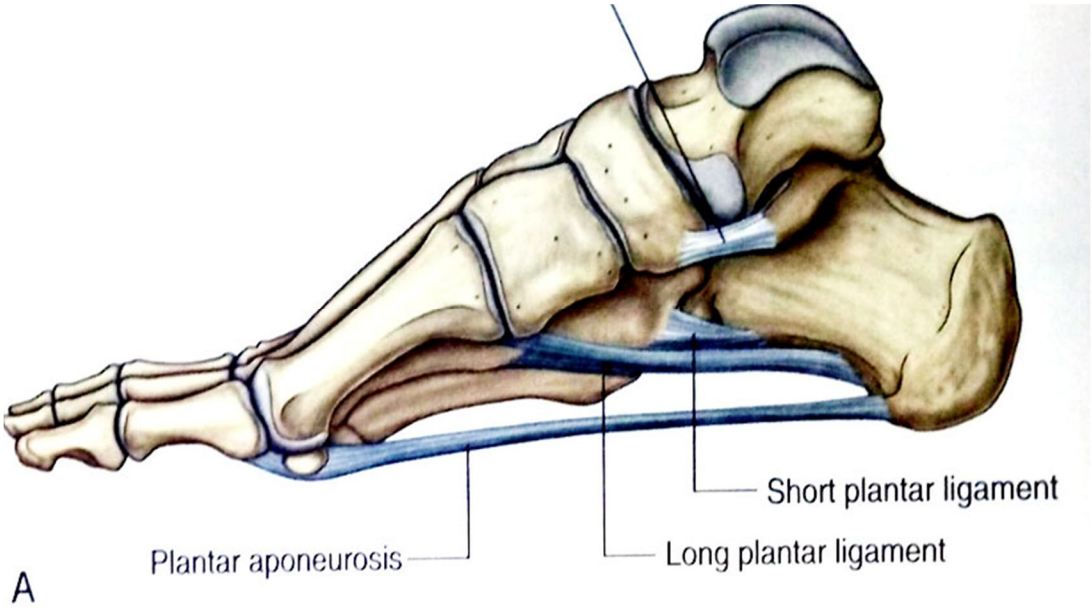

Fig 5-Supports to the arches of foot[11]

PLANTAR FASCIITIS:

Definition:

'It is the condition that occurs as a result of degenerative process of plantar fascia at its attachment to the calcaneal tuberosity'.

Epidemiology :

Plantar fasciitis is the most common cause of chronic heel pain in adults affecting 7 to 10% of population[3].Every 1 in 10 people will develop PF during their life peroid[12]. There is incidence of 8% of PF of all sports related injuries[13]

PF usually occurs between age group 45 to 64 yrs. Rano et al in their study says that patient with PF attending their clinic found to be 10 yrs more than those coming for other condition.

Plantar fasciitis is more common in middle aged females, overweight and obese persons, young sports person, person with occupation requiring prolonged standing and doing sedentary work[15].

Previous studies does not clearly explain the prevalence of PF in males and females. Taunton et al in their study says the prevalence of PF is more in males whereas Raono et al shows more prevalence of PF in females.[14]

If the patient had one side heel pain, then they will compensate it by using opposite leg, then subsequently both heel develops pain but the side with main symptomatic side is considered and treated first. Nearly one- third of patients present with bilateral plantar fasciitis in most studies.[16]

Plantar fasciitis also called as painful heel syndrome, calcaneal periostitis, heel spur syndrome, chronic plantar heel pain and runner's heel ,jogger's heel, policeman's heel, tennis heel[17].

Also called Plantar fasciosis due to chronicity of the disease and because of degeneration than inflammation. There is no role of ethinicity and race in the incidence of plantar fasciitis.

Usually the symptoms will last for 6 month-1year in most patients. Previous two cohort study shows the mean duration of symptoms ranges from 13.3 to 14.1 months[18.]

The American Podiatric Medical Association conducted a survey recently which shows that plantar fasciitis was the most common condition treated in podiatric clinics[19]

Etiology:

The exact cause of painful heel is still unclear. Main risk factors for plantar fasciitis is prolonged standing , weight bearing activities, obesity etc.

Risk factors are mainly divided into intrinsic and extrinsic risk factors. The intrinsic risk factors are pes planus, pes cavus, over pronated foot, leg length discrepancy, increased tibial torsion and increased femoral anteversion.

The extrinsic risk factors are improper atheletic shoes, plyometric workouts, running on poorly cushioned surfaces during training etc[20].

Previous studies shows that in runners ,the risk factors like varus in hind foot, pes cavus, spiked shoes, running in the street were related to onset of plantar fasciitis[21].

Ying et al in their study reported that incorrect tight foot wear also found to be a risk factor for Plantar fasciitis[22`].One study shows that changing shoes during work week in assembly plant workers reduces the risk factor for developing plantar fasciitis[23].

Foot biomechanics also one of the common risk factors for development of PF like hyper pronation of foot, pescavus, pes planus and increased metatarsal pressure[23]

There is correlation between chronic heel pain and obesity. In one study BMI about 35±4.5 kg/m^2 are more prone to develop Plantar fasciitis[24]

There is increased risk factor of Plantar fasciitis with limited ankle dorsiflexion. For normal walking ,knee extension and ankle dorsiflexion about 10 degree is needed, if there is contraction of tendoachilles, there will be deceased ankle dorsiflexion and compensatory hyperpronation of foot leading to increased tensile loads on plantar fascia[25.]

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PATHOPHYSIOLOGY:

The main functions of the foot are providing propulsive forces in late stance of gait cycle and to restore the body weight in early stance phase. For this the foot should be flexible and soft while bearing weight and then has to become rigid and tense during push off phase of gait cycle. This is produced by plantar fascia which became as truss during absorption of force and acts as a taut band to give rigidity during propulsive phase of gait cycle.

Due to increasing age there will be degenerative changes in the elastic adipose tissue of the heel pad and there is also gradual reduction in collagen, elastic fibrous water content

In 1954 Hicks, postulated windlass mechanism of PF when the toes are dorsiflexed. PF originates from anteromedial aspect of the calcaneal tuberosity and attached by several slips into plantar plates of the metatarsophalangeal joints, the flexor tendon sheaths, and the bases of the proximal phalanges of the digits, put them under constant traction when it is pulled distally around the drum of the metatarsal heads acting as windlass.

This mechanism will cause tightening and elevates the longitudinal arch thereby producing traction on the origin of the plantar fascia[9].

Woolnough called this PF as Tennis heel as due to repetitive traction and aging leads to cystic degeneration and microscopic tears in the origin of plantar fascia and flexor digitorum brevis which present beneath plantar fascia.

Plantar fascia which act as a supporting structure of the longitudinal arch of the foot has been studied by Kitaoka et al and Murphy et al, shown that significant changes will occur in the in the longitudinal arch after surgical resection of plantar fascia leading to arch pain[9]

There is reduced vascularity and nutritional blood flow through the impaired plantar fascia making the cells difficult to synthesize the extracellular matrix for repair and remodelling[26]

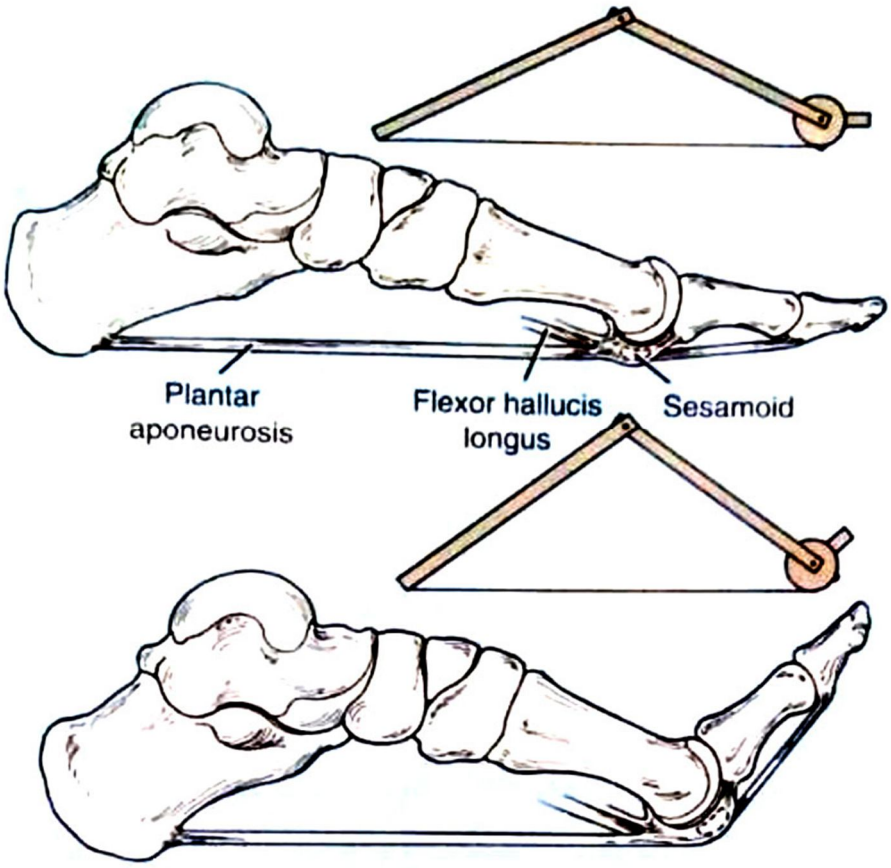


Fig 6-Windlass mechanism[9]

HISTOLOGY:

There will be marked thickening of plantar fascia, myxomatous degeneration, disorganized collagen fibres, micro tears, connective tissue calcium deposits[27]. So histologically plantar fasciitis is better defined as Plantar fasciosis. In one retrospective study,25% of the pathological specimen of chronic plantar fasciitis shows the histological appearance of plantar fibroma[1]

CLINICAL PRESENTATION:

The major complaint will be pain beneath the heel that became worse on rising in the early morning or sitting for a while. Pain may be in medial, lateral, lower posterior and inferior heel region, but most commonly in medial heel. sometimes patient may also complain pain over central band of plantar fascia in the region of the medial longitudinal arch[5].

After a few steps of walking, there will be decrease in pain and patient will feel aching pain during the end of day that will be relieved by discontinuing weight bearing[9].

On examination there will be localised tenderness in inferomedial aspect of the calcaneal tuberosity. Windlass test is done by dorsiflexing great toe and ankle producing more pain is positive in most of the cases.

Negative Tarsal Tunnel Tests and lower limb tension and sensation tests.Negative lumbosacral and neurological examination to rule out other causes of plantar fasciitis[28].

Classification of Plantar Fasciitis[1]:

The ICD-10 code of plantar fasciitis is M72.2. The primary ICF body Function codes associated with plantar fasciitis are b28015 pain in the lower limb. The primary ICF body structure codes associated with PF are s75023 Ligaments and fascia of ankle and foot.According to this we should ask in history and examine the relevant test to rule out Plantar fasciitis.

- Plantar heel pain medially with early morning heel pain which became worse on weight bearing.
- Recently heel pain precipitated by increases in weight bearing.
- Tenderness on palpation of plantar fascia over medial calcaneal tuberosity.
- Windlass test-Positive.
- Tarsal tunel test-Negative.
- Ankle ROM-passive and active dorsiflexion restricted.
- FPI Score-abnormal.
- BMI –Increased in nonatheletes.

DIFFERENTIAL DIAGNOSIS[15]:

1. Retrocalcaneal bursitis-pain will be in the retrocalcaneal region and pain will aggravate by passive dorsiflexion.
2. Tarsal tunnel syndrome-there will be radiating pain from medial malleolus and spreads upto foot.
3. S1 Radiculopathy- there will be radiating pain from lower back to posterior aspect of leg.
4. Lateral plantar nerve entrapment-pain in the lateral plantar aspect of foot.
5. Peripheral neuropathy-there will be numbness and tingling pain in foot which is diffuse in nature.
6. Acute calcaneal body fracture-history of injury.
7. Calcaneal stress fracture-dull aching pain in calcaneal tuberosity increased by walking on uneven surfaces.
8. Subtalar arthritis-heel pain which is insidious in onset and relieved by taking rest.
9. Acute plantar fascia rupture-plantar pop with heel pain and swelling of foot.
10. Fat pad atrophy-central heel pain increased by walking on hard surfaces.
11. Insertional Achilles tendonitis-posterior heel pain increased by walking upstairs.

INVESTIGATIONS:

1. Complete blood count.
2. Blood glucose.
3. Erythrocyte sedimentation rate.
4. RA factor.
5. C-reactive protein.
6. Imaging of ankle with foot.

IMAGING STUDIES:

1. Plain X-ray ankle with foot-AP and lateral view:

Presence of bony spur on the calcaneum. The incidence of heel pain with bony spur is reported to be 59% in one study[29]. Plantar calcaneal bone spur present along with plantar fasciitis in most cases. A calcaneal spur is an ossoeus protrusion located in the medial calcaneal tuberosity due to tension placed on bone from the structures originating from there. In a study radiograph taken from 1000 patients with heel pain shows incidence of 13.2% to have calcaneal spur[5].

2.Ultrasonagraphy:

Diagnosis of plantar fasciitis is made in ultrasonagraphy by increased signal intensity of PF, thickness of plantar fascia more than 4mm,hypoechogenic plantar fascia, alteration of heel pad signal[13].

3. Real time sonoelastography:

This technique finds whether tissues are less or more elastic and used in diagnosis and planning for intervention in PF[6]

4.MRI ankle with foot:

Shows calcaneal edema with increased T2 signals in plantar fascia and thickening of plantar fascia on T1 images and classified into mild,moderate,severe plantar fasciitis depending on edema and tearing[30].

5.Bone scan:

There will be increased isotope uptake in anteroinferior medial aspect of the calcaneus.It can also rule out stress fracture and helps in clear diagnosis[9]

6.Electromyography:

EMG of abductor digiti minimi done to rule out tibial nerve entrapment.

TREATMENT :

As this is self limiting disease but duration of disease varies from one patient to other ranging from 6 months to 2yrs.

MEDICAL MANAGEMENT:

1. **NSAIDS**:

They act by inhibiting synthesis of prostaglandins and has anti inflammatory,analgesic and antipyretic action.but NSAIDs did not suppress the production of leukotrienes,platelet activating factor,cytokines[31].

Adverse effects:

Long term use of NSAIDs leads to Gastritis ,peptic ulcer,sodium and water retention,hepatic complications.

2.ORAL STEROIDS:

Lapidus and Guidotti reported that all 364 painful heels in 323 patients responds well to use of oral steroids[9]

3. LOCAL CORTICOSTERID INJECTION:

Methyl prednisolone:

Methyl prednisolone is one of the intermediately acting glucocorticoids which act by inhibiting leukocyte infiltration at the site of inflammation and also inhibits mediators of inflammation such as prostaglandins and leukotrienes.

It is metabolised in liver and excreted by kidneys. The onset of action is rapid during intra atricular injections and half life is about 1-2 days. The duration of action will peak in 7 days and last upto 11/2 months.

Relative contraindications:

- Uncontrolled Diabetes milletus.
- Local infection.
- Osteoporosis.
- Renal disease.
- Uncontrolled hypertension.
- Ulcerative colitis

Complications[1]:

- Fat pad atrophy.
- Local site erythema.
- Plantar fascia rupture-It leads to instability of calcaneocuboid joint and instability of the lateral column. Usually it occurs in 2.4-5.7% of cases[30].
- Changes in Skin pigmentation.
- Nerve injury.
- Damage to muscle.

Crawford et al. described prednisolone with lignocaine injections provide short term relief in plantar fasciitis.

Andrew et al in their study shows that Plantar fascia thickness reduced significantly at 8 and 12 weeks[32].

BOTULINUM TOXIN INJECTION:

Botulinum Toxin –A is a neurotoxin produced by clostridium botulinum.It is a gram positive bacteria.

There are seven serotypes of BTX namely type A,B,C(C1,C2),D,E,F and G.Mainly type A and type B are used.

The various types of BTX A namely Onabotulinum toxinA,Abobotulinum toxin and Incobotulinum toxin A.BTX type B is Rimabotulinum toxinB[8].

Onabotulinum toxinA:

It is used in cervical dystonia,migrane,spasticity,detrusor hyperactivity, squint, blepharospasm and recently in musculoskeletal pain management.

Abobotulinum toxinA:

It is used in lower limb spasticity in childrens,cervical dystonia.

Incobotulinum toxinA:

It is used same as above and also for sialorrhea.

Rimabotulinum toxinB:

It is also used in cervical dystonia.

Chemical structure:

The chemical structure of Botulinum is single chain molecule with molecular weight about 150kD.

They form dichain molecule with disulphide bridge after cleavage.They are light and heavy chain molecules.The light chain has proteolytic activity and heavy chain has cholinergic properties.This heavy chain will bind the toxin to the presynaptic receptors[33].

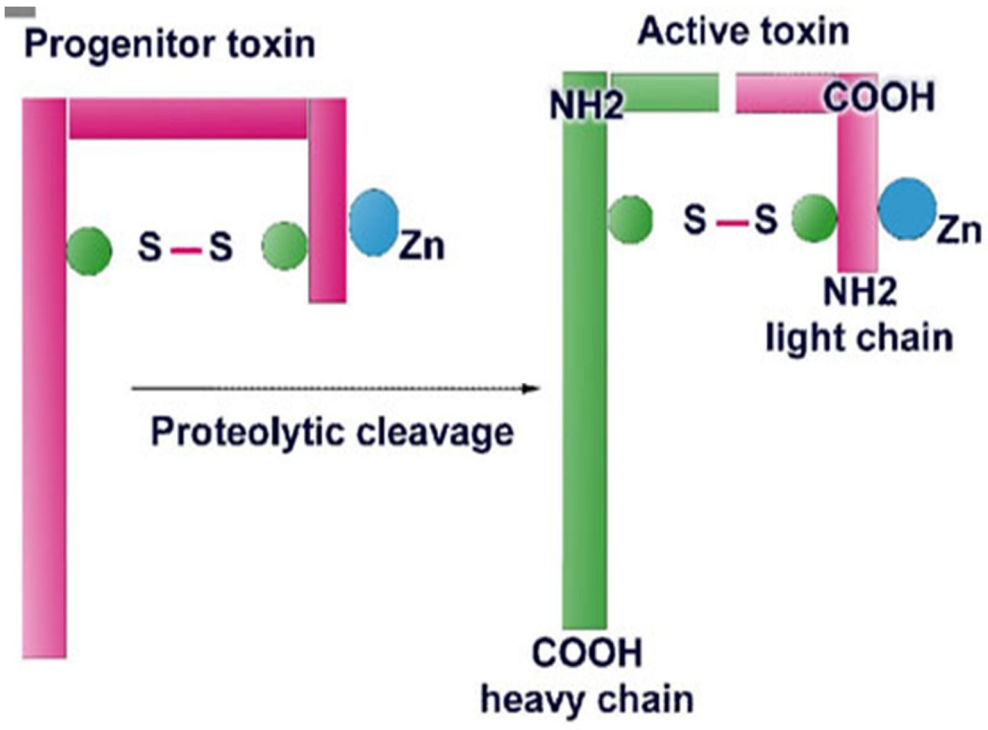


Fig 7:Chemical structure of Botulinum toxin[33]

Mechanism of action of Botulinum Toxin:

The main action of this drug is it reversibily inhibit presynaptic release of neurotransmitters at the NMJ .The main neurotransmitter is acetyl choline which leads to muscle weakness[34].

Botulinum toxin A and E-Both act by cleaving synaptosomal proteins SNAP25 which is needed for fusion of neurotransmitters containing vesicle[36].

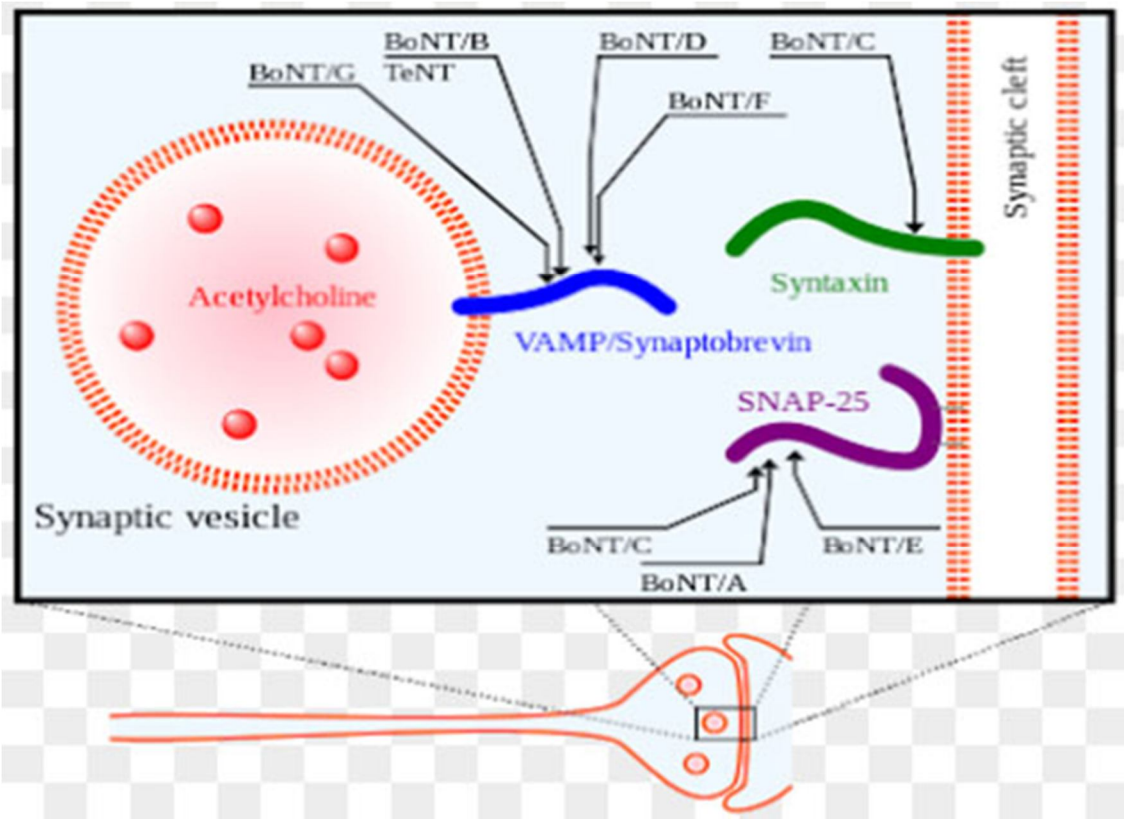


Fig 8-Action Of Botulinum[35]

Botulinum toxin B,D,F are called synaptobrevin and they act by cleaving vesicle associated protein.

Botulinum toxin C called as syntaxin and they cleave target membrane protein.

Botulinum Toxin-A has been found to have antinociceptive and anti allodynia effects. It also acts by modulating pain neurotransmitters like substance p,glutamate and anti-inflammatory reactions[6]

In a study, Botulinum toxin-A injected into 22 patients with PF shows improvement lasting for 8 weeks[37].

Botulinum toxin- A also found to inhibits peripheral sensitization which leads to an indirect reduction in sensitization[38]

The action of BTX-A in the treatment of myofascial pain is through the blockade of acetylcholine release from the presynaptic vesicle thereby relieving muscle spasm and pain.The blockade of acetyl choline in turn produce anti inflammatory action[39]

Babcock proposed a mechanism of action by which BTX-A injected into a muscle result in transient loss of muscle volume via induction of muscle atrophy

which in turn relieves pressure on the neurovascular structures trapped under a tight plantar fascia[40].

Purkiss et al in their study says that in dorsal root ganglia calcium dependent release of substance P is inhibited by Botulinum and thereby inhibiting C and A delta fibres producing an analgesic effect[41].

Preparations of BTX:

BTX available in freeze dried vial of 50,100 units with normal saline for dilution. BTX should be used within four hours after reconstitution. Potency of BTX is measured by mouse units(MU). The lethal dose is 2500-3000U.Median paralysis unit (MPU) is used as the unit of biological activity[33].The effect of toxin usually seen within 7-10days.Maximum response occur within 1½ months and last for 3-4 months.

Side effects:

Local injection site erythema, muscle paralysis, flu like syndrome, seizures[33].

Jamal ahmad et al in their study showed that Incobotulinum toxin provided significant pain relief in chronic plantar fasciitis in comparison with normal saline[34].

In another study,treatment of plantar fasciitis with BTX A gives pain relief and decrease in PF thickness at 3 weeks and 3 months after intervention and it gives better results when given under ultrasound guidance[6].

PLATELET RICH PLASMA THERAPY:

PRP is prepared from autologous whole blood which contains an increased concentration of autologous platelets. The cytokines and growth factors present in PRP play a major role in treatment of PF.PRP also has some anti-inflammatory cytokines and leukotrienes which initiates the healing stages and to reverse the degenerative process of PF[44].

In one study PRP was found to be more effective than corticosteroid in treating chronic plantar fasciitis[45].

There was significant improvement in VAS and AOAFS score with PRP intervention at 3 weeks and 3 months in another study[46].

PROLOTHERAPY:

The injection of dextrose with lignocaine initiates the body's wound healing cascade of inflammation, granulation tissue formation and matrix formation and remodelling[47]

Kim et al and Ryan et al reported a significant reduction in pain after prolotherapy treatment for PF[48,49].

SURGICAL MANAGEMENT:

- Open plantar fascia release or minimally invasive percutaneus plantar fascia release[50].
- Exposure of entire heel pad through horse shoe incision and release of all soft tissue origins from the anterior aspect of calcaneal tuberosity[9] (Griffith).
- Snook and Chrisman excised the medial tubercle of the calcaneus with accompanying spur[9].

Jorge Elizonda-Rodriguez et al in their study says that surgical complications will leads to decreased stability of arch and subsequently decreased stability during terminal stance phase of gait cycle[30].

Physiotherapy:

1. Stretching exercise to plantar fascia which is done by dorsiflexing toes, holding the metatarsophalangeals and stretching fascia in arch region. It is done by rolling arch over water bottle or by leaning against the wall. Each stretch is maintained for 30 seconds with knees straight and heels on the ground[51].

2. Towel stretch:

   Stretching exercise to Achilles tendon done with the help of towel. Dorsiflexion of foot and holds that stretch for a minimum of 30 seconds 10 times.

3. Strengthening and stretching exercise to intrinsic muscles of foot- crunching the towel with toes, picking up the marbles.

4. Stretching exercise to hamstring muscle.

5. Evidence from two systemic reviews suggests stretching of the ankle and foot provide short term clinical benefit with plantar fasciitis[52.53]

A more recent systemic review by sweeting and collegues concluded that the main pain-relieving benefits of stretching appear to occur within first 2 weeks to 4 months but could not support one method of stretching over other[53].

Stretching exercise to plantar fascia and tendo Achilles will recreate windlass mechanism[30].

Physical modalities:

- Icing .Application of ice intermittently gives better pain relief.
- Deep transverse friction massage.
- Taping of the foot.

Tsai et al showed that therapeutic elastic taping applied to plantar fascia and gastronemius reduces pain scores in comparison to ultrasound and electrotherapy after 1 week in plantar fasciitis[54].

- Ultrasound therapy,ionotophoresis or phonophoresis.

5% acetic acid or 0.4% dexamethasone applied through ionotophoresis will reduce pain for upto 4 weeks, but Cleland et al in their study shows no improvement in ionotophoresis over 4 week period in comparison to manual therapy[55].

- Low level Laser therapy.

Kiritsi et al showed the same results in regards to effects of gallium – arsenide infrared didode laser in comparison with placebo in plantar fasciitis[18].

- Extra corporeal shock wave lithotripsy-using electrohydraulic shock wave under intravenous sedation. Landorf And Menz found that this ESWT does not give better results and adverse effects are reported[52].

- Night splints:

It will maintain the ankle in dorsiflexion and extension of toes thereby producing constant stretch of PF and allow it to heal at functional length.

Lee et al found that night splints along with foot orthosis gives better pain relief in plantar fasciitis[56].

- Custom made foot orthosis supporting medial longitudinal arch.

Hawke et al found that custom foot orthosis were more effective than sham orthosis in improving function only,but pain score not reduced[57].

- Cushioning to heels.
- Dry needling.

Patient education and counselling:

- Modify weight bearing loads during daily activities, occupation and during sports activities.
- Proper foot wear options.
- To maintain optimal lean body mass[1].

Prognosis:

The long term prognosis of plantar fasciitis is unknown. Usually the condition will resolve in 1 to 2 yrs. In one study there is still risk of having PF after 5 years was 50%,45.6% after 10 yrs and 44% after 15 yrs from onset of symptoms[3].

Pain related fear of movement and fear avoidance behaviour is one of the contributor to disability in plantar fasciitis[58].

Materials & Methods

MATERIALS AND METHODS

Study centre:

Government Institute of Rehabilitation Medicine, K.K Nagar.(Madras Medical College, Chennai).

Duration of study:

9 months (20^{th} December 2017-20^{th} september 2018).

Study Design:

Prospective assessor and therapist Blinded ,Simplified Randomized Controlled Clinical trial study.

Sampling:

100 Participants were selected according to inclusion and exclusion criteria from individuals attending PMR-OPD.

Randomization:

Selected Participants were randomized(1:1) to one of the treatment group(1 or 2) by simplified sampling method.

Blinding:

Participants and physiotherapist were blinded to know about the treatment of the participant.

Proposed Treatment Groups:

- Group 1: will receive Botulinum toxin-A injection and scheduled exercise therapy.
- Group 2: will receive methyl prednisolone acetate injection and same scheduled exercise as group 1 for 6 months

Sample Size : 50+50.

INCLUSION CRITERIA

- Age 20-60 yrs.
- Symptomatic heel pain for 3 months.
- Heel pain with anatomical derangement of foot.
- Presence of calcaneal spur in x-ray.
- Both sex(male and female).
- Either side(right or left heel).
- Early morning heel pain.
- No improvement of heel pain after physical modalities.

EXCLUSION CRITERIA

- Any systemic disease with foot pain like rheumatoid arthritis etc.
- Any surgery in foot.
- Known allergy to Botulinum toxin.
- Pregnant women.

- Breastfeeding women.
- Patient on anticoagulation.
- Neuromuscular junction disorder.
- Any local steroids within 3 months.
- Any cellulitis of foot.
- Uncooperative patients.
- Psychiatric patients.
- Malignancy.
- Uncontrolled diabetes.
- Bleeding disorders.

METHODOLOGY:

After obtaining informed consent and routine general examination, participants will be administered test dose of 2% lignocaine and after confirming there is no adverse reactions, participants were taken to operation theatre and involved foot with ankle will be cleaned with surgical spirit followed by povidone iodine and then covered around by sterile towel.

Under strict aseptic precautions, the injection site is anaesthesized with 2ml of 2% lignocaine.

- Group 1 will receive 50 units of Botulinum toxin-A mixed with 1ml of normal saline, injected into most tender point on medial aspect of heel.
- Group 2 will receive 40 mg of Methyl prednisolone acetate injection into most tender spot on medial aspect of heel.

After intervention participants will be observed for 15 minutes for any adverse reactions and the participants also instructed to report any adverse reactions immediately.

Group 1 and 2 will receive scheduled exercise therapy like stretching exercise to plantar fascia,tendoachilles hamstrings and intrinsic foot muscle exercise.

The participant, the physiotherapist seeing the participant will be blinded and do not know about the treatment received.

Products Details:

Botulinum Toxin-A-50 Units.

Methyl prednisolone acetate-40 mg.

SCREENING PROCEDURE

- Detailed history taking, clinical examination of foot.
- Investigation such as fasting and postprandial blood sugar, x-ray ankle with foot, thickness of plantar fascia by ultrasonagram.

Data collection and methods:

Participants were assessed before and after treatment at 1 month, 2 months, 4 months, 6 months after intervention using Visual Analogue Scale, FAAM Score according to protocol as submitted. Participants in each group should follow exercise protocol after intervention.

Statistical analysis:

Analysis was done using standard software.

Sponsorship : No.

Ethical Issues:

Prior to the commencement, the study was approved by the Ethical and Research Committee, Madras Medical College.

Informed Consent:

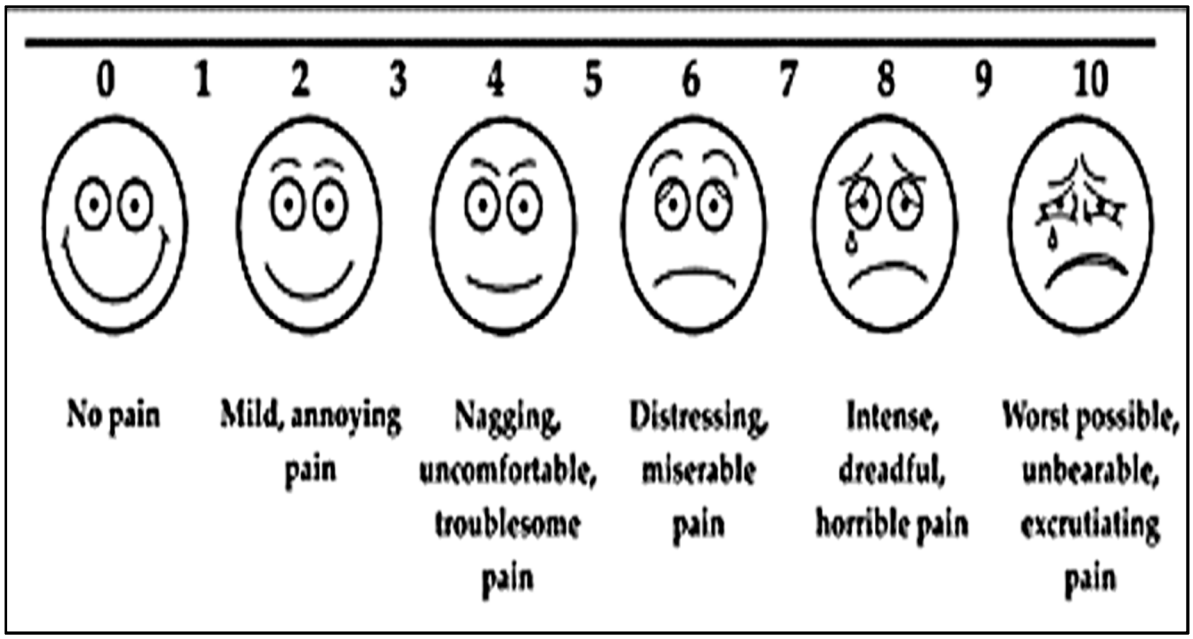
Participants selected according to the protocol were briefed about the nature of the study. A written informed consent was obtained from them (Annexure)

Outcome scales used:

Visual analogue scale:

It is the most common subjective outcome scale used to measure pain intensity level[63]. The VAS scale at one end has no pain level and end with worst pain at other end. It also has numeric value from 0 to10.

VISUAL ANALOGUE SCALE



Foot Ankle Ability Measure:

This is one of the outcome scale used to assess the physical function of the patients with ankle and foot related impairments[64].This scale has two subscales.

1) 21 item activities of daily living.
2) 8 item for sport subscale.

As the sport subscale is specific for atheletes ,only ADL subscale is only taken here for assessment.

Each item is scored on a 5 point Likert scale with 4 to 0.

- Score 4-No difficulty at all.
- Score 3-slight difficulty.
- Score 2-moderate difficulty.
- Score 1-extreme difficulty.
- Score 0-unable to do.
- N/A-not applicable

Total score of item range from 0 t0 84 are then transformed into percentage score with 100% considered as no dysfunction.

Foot and Ankle Ability Measure (FAAM)

Please answer **every question** with the **one response** that most closely describes your condition within the past week. If the activity question is limited by something other than your foot or ankle mark N/A (not applicable).

	No Difficulty	Slight Difficulty	Moderate Difficulty	Extreme Difficult	Unable to do	N/A
1. Standing	☐	☐	☐	☐	☐	☐
2. Walking on even ground	☐	☐	☐	☐	☐	☐
3. Walking on even ground without shoes	☐	☐	☐	☐	☐	☐
4. Walking up hills	☐	☐	☐	☐	☐	☐
5. Walking Down Hills	☐	☐	☐	☐	☐	☐
6. Going up stairs	☐	☐	☐	☐	☐	☐
7. Going down stairs	☐	☐	☐	☐	☐	☐
8. Walking on uneven ground	☐	☐	☐	☐	☐	☐
9. Stepping up and down curbs	☐	☐	☐	☐	☐	☐
10. Squatting	☐	☐	☐	☐	☐	☐
11. Coming up on your toes	☐	☐	☐	☐	☐	☐
12. Walking initially	☐	☐	☐	☐	☐	☐
13. Walking 5 minutes or less	☐	☐	☐	☐	☐	☐
14. Walking approximately 10 minutes	☐	☐	☐	☐	☐	☐
15. Walking 15 minutes or greater	☐	☐	☐	☐	☐	☐

Because of your foot and ankle how much difficulty do you have with:

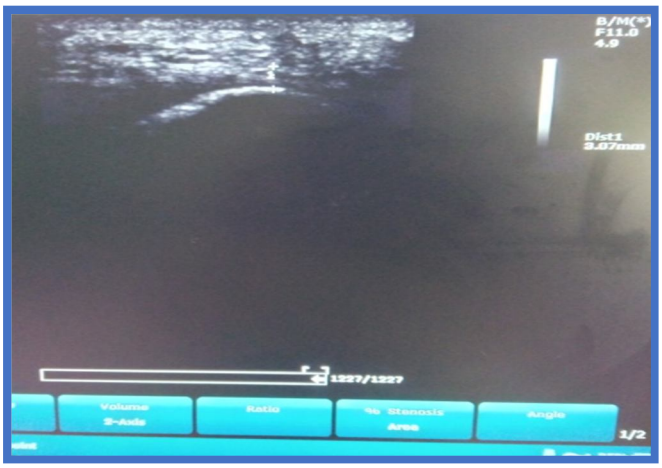
16. Home responsibilities	☐	☐	☐	☐	☐	☐
17. Activities of daily living	☐	☐	☐	☐	☐	☐
18. Personal care	☐	☐	☐	☐	☐	☐
19. Light to moderate work (Standing or walking)	☐	☐	☐	☐	☐	☐
20. Heavy work (pushing/pulling, Climbing, carrying)	☐	☐	☐	☐	☐	☐
21. Recreational activities	☐	☐	☐	☐	☐	☐

How would you rate your current level of function during your usual activities of daily living from 0 to 100 with 100 being your level of function prior to your foot or ankle problem and 0 being the inability to perform any of your usual daily activities?_____%

Name (Please Print)_____ Date ___/___/_____

INVESTIGATION

TEMPLATE-1



TEMPLATE 2 – Intervention

TEMPLATE-3 – Exercise therapy

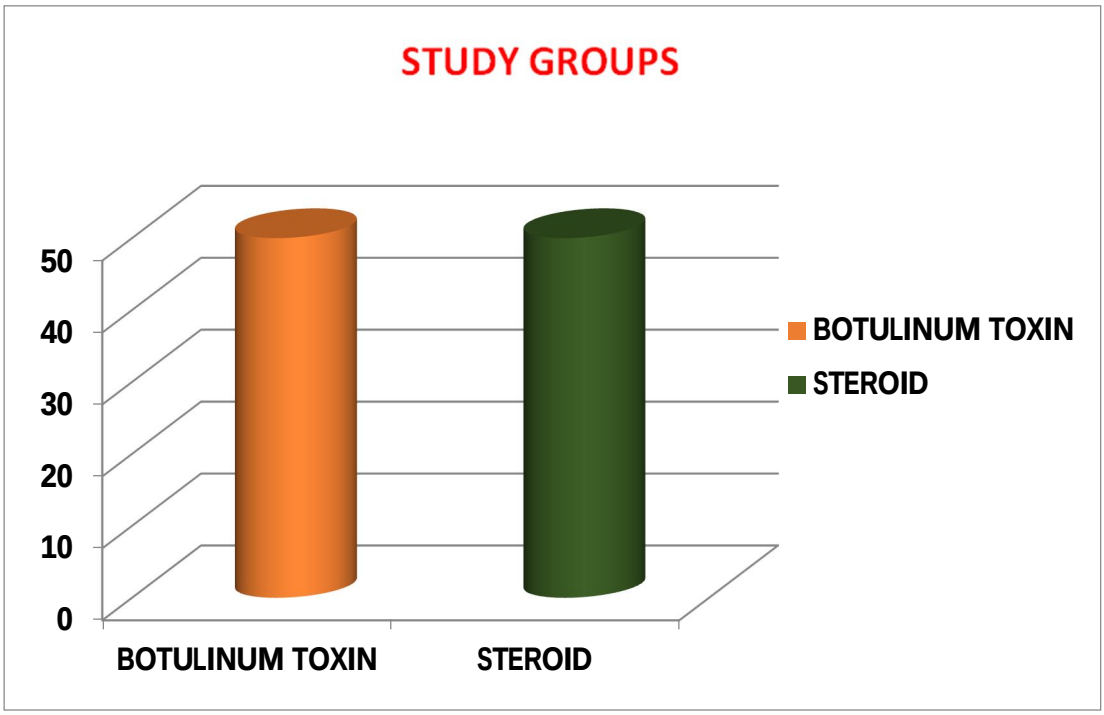
Observation Results & Analysis

OBSERVATIONS, ANALYSIS AND RESULTS

DEMOGRAPHIC FEATURES:

Sample Size and Study Groups :

CHART 1



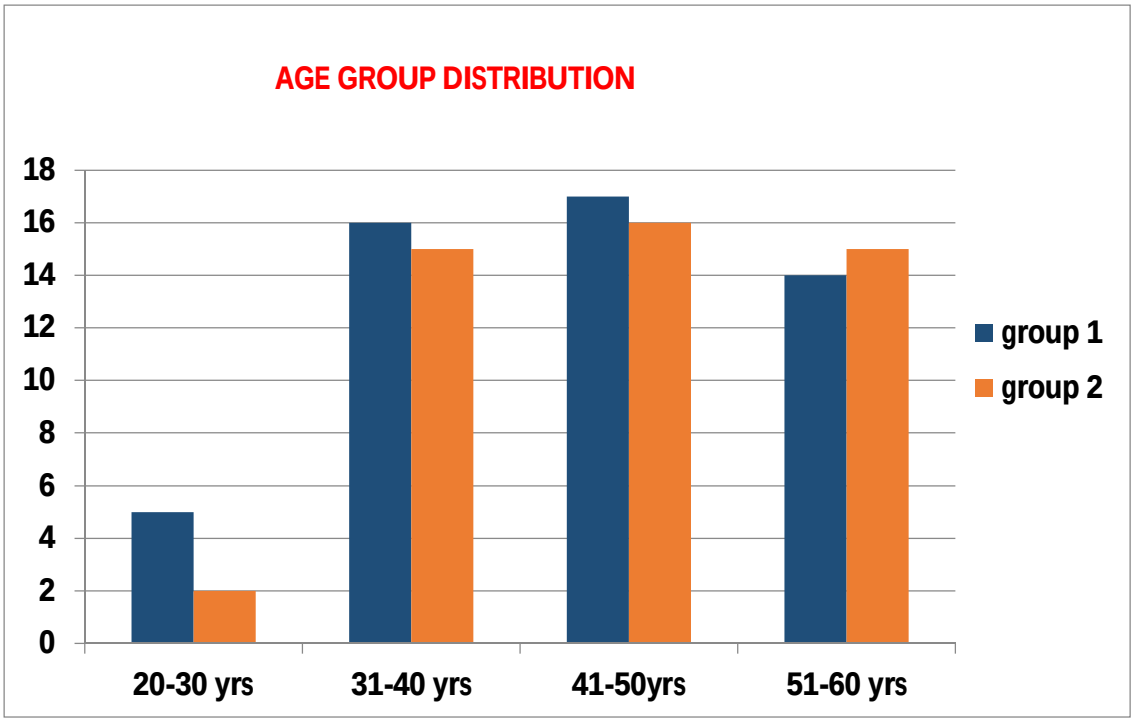
Totally 100 participants were included in the study with 50 participants in each group(Group1:Group2).Mostly the participants belong to low and moderate socio economic status. 11 participants in group 1 and 8 participants in group 2 didn’t come for follow up in 8 month.

AGE:

TABLE 1:DEMOGRAPHY-AGE

Group	N	Minimum Age	Maximum Age	Mean Age	Standard Deviation	P value
1.Botulinum Toxin	50	22	60	44.6	9.66	0.96
2.Steroid	50	23	60	44.8	9.75	

CHART 2



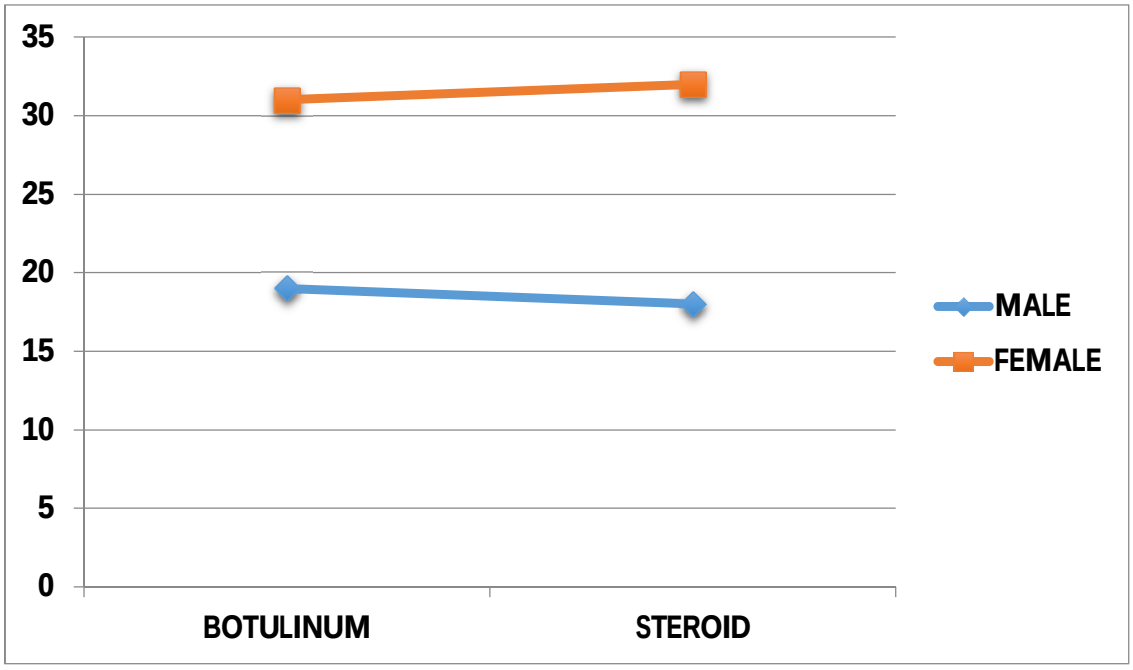
Most of the participants were between 31 to 40 yrs and between 41 to 50 yrs in our study.The mean age years affected by PF is 44.6yrs in groups 1 and 44.8yrs in group 2.

SEX:

TABLE 2 : DEMOGRAPHY-SEX

Group		Frequency	Percent	P value
1.Botulinum Toxin	Male	19	38	
	Female	31	62	0.83
	Total	50	100	
2.Steroid	Male	18	36	
	Female	32	64	
	Total	50	100	

CHART 3 : SEX DISTRIBUTION



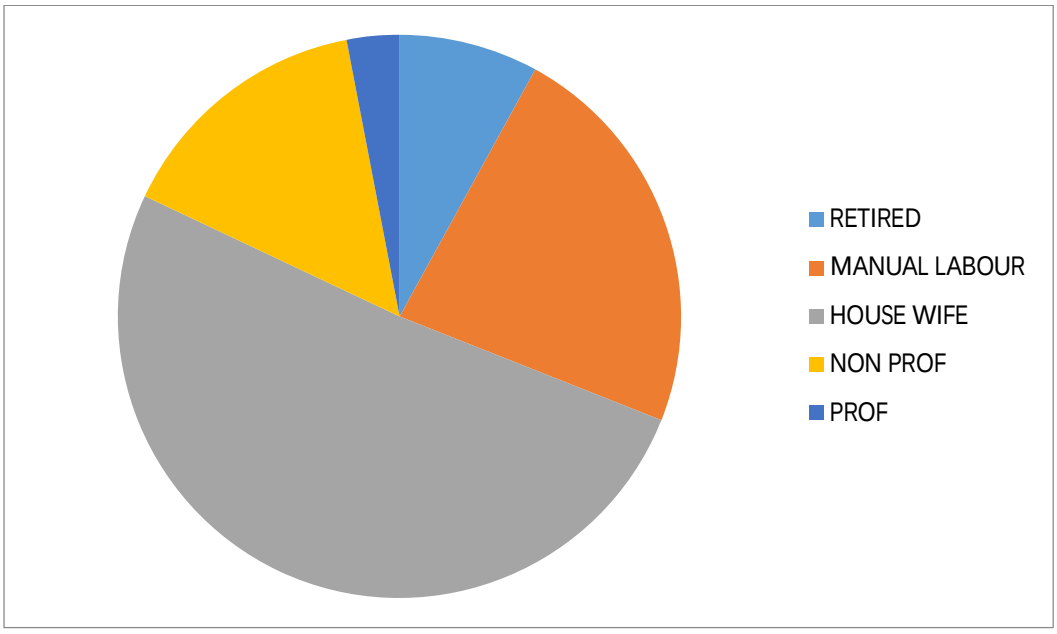
In our study female participants are more than male participants.In group 1 there was 19 males(38 %) and 31 females(62%).In group 2 there was 18 males(36%) and 32 females(64%).

OCCUPATION:

TABLE 3- TYPE OF WORK

	N	Frequency
Retired	100	8
Manual labourer		23
House wife		51
Non professional		15
Professional		3

CHART 4-TYPE OF WORK



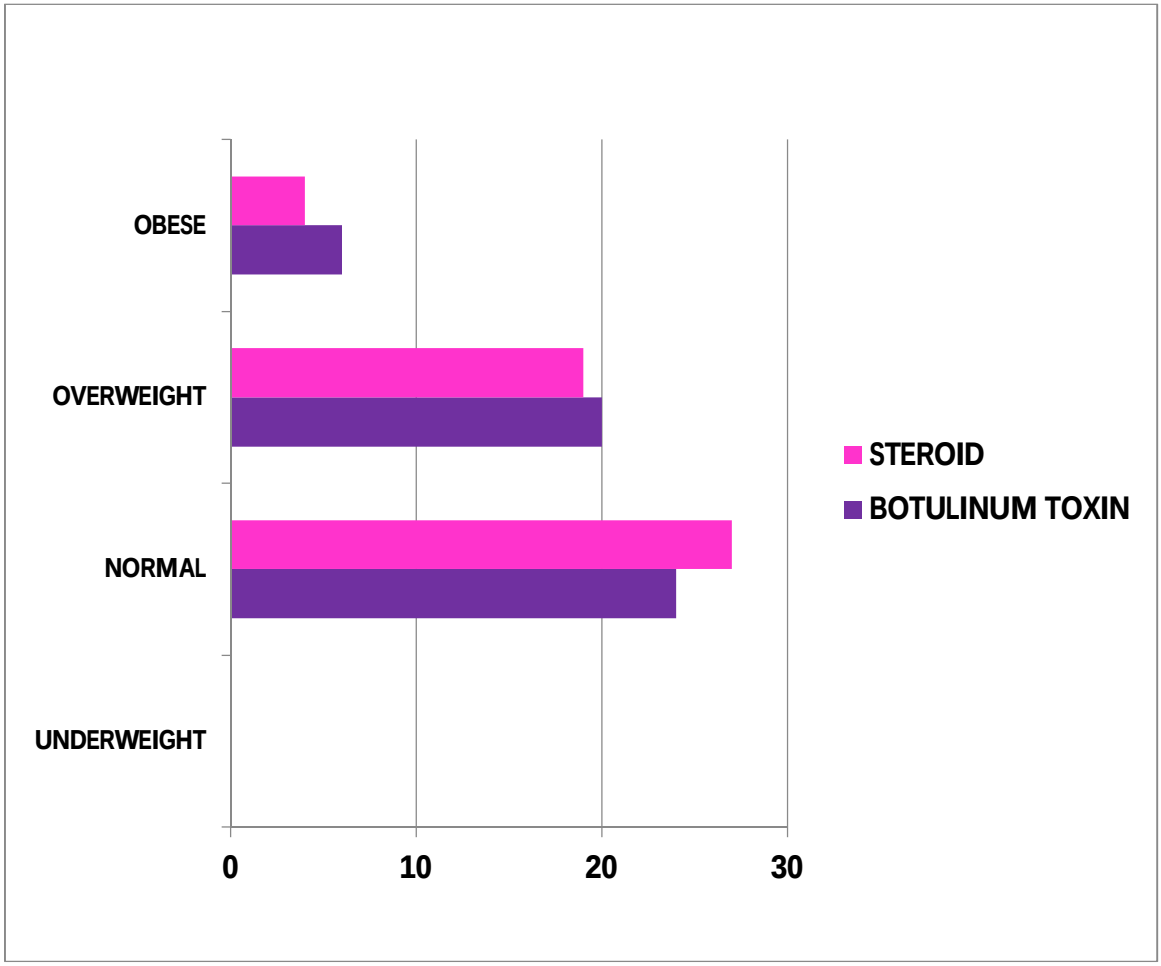
According to type of work,participants were analysed regarding correlation between work and incidence of plantar fasciitis.Among Them house wives are more prone to plantar fasciitis,followed by manual labourers. But their nature of work,standing time are not assessed in this study.

BODY MASS INDEX:

TABLE 4: BMI

Group	N	Category	Frequency	Percent
1.Botulinum Toxin	50	Underweight	0	0
		Normal	24	48
		Overweight	20	40
		Obese	6	12
2.Steroid	50	Underweight	0	0
		Normal	27	54
		Overweight	19	38
		Obese	4	8

CHART 5-BMI



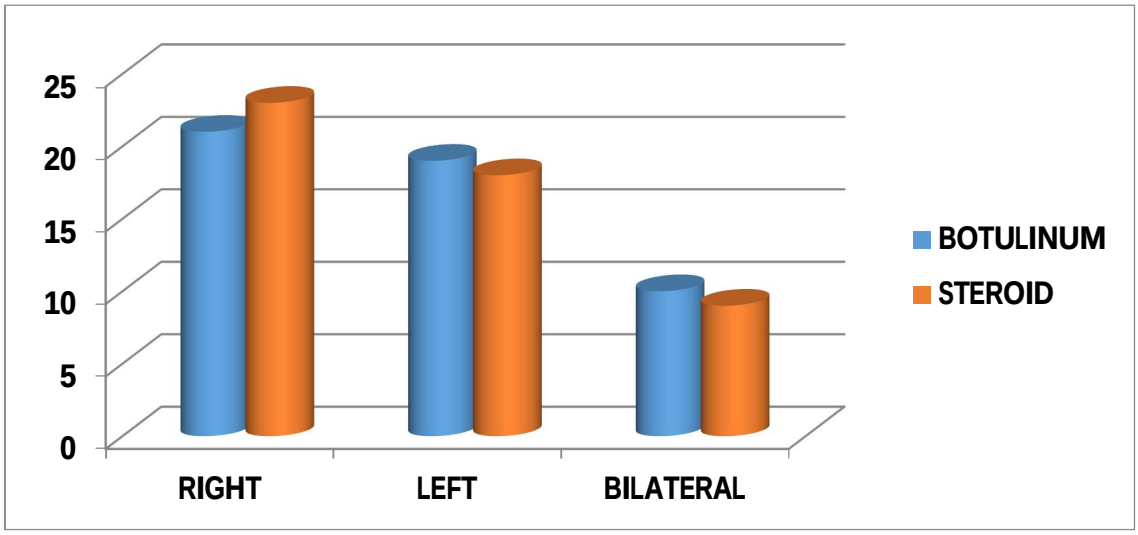
In this study in group 1 there was 20(40%) overweight and 6(12%) obese participants.In group 2 there was 19(38%) overweight and 4(8%) obese participants.Body mass index results proves that overweight and obesity is one of the risk factor of PF.

SIDE OF HEEL PAIN:

TABLE 5: SIDE OF HEEL PAIN

Group	Side	Frequency	Percent
1.Botulinum Toxin	Right	21	42
	Left	19	38
	Bilateral	10	20
2.Steroid	Right	23	46
	Left	18	36
	Bilateral	9	18

CHART 6 - LATERALITY OF HEEL PAIN



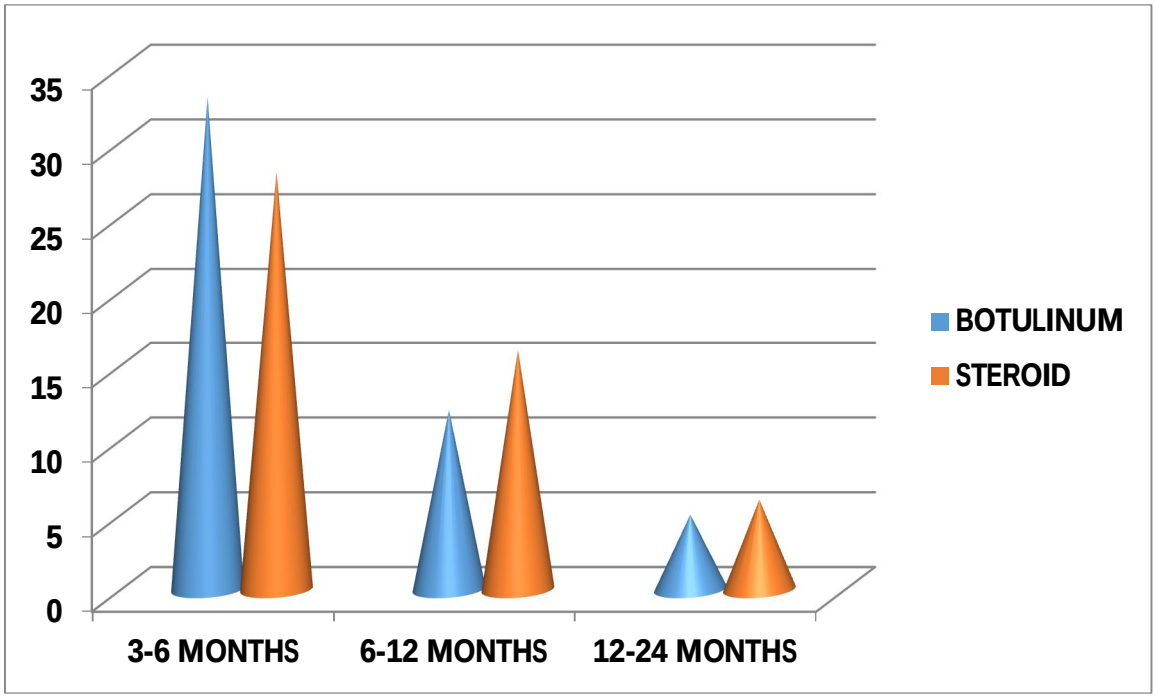
In our study,in group 1 the participant with heel pain in the right side is 21(42%), left side is 19(38%) and bilateral side 10(20%).In group 2 the participant with heel pain in the right side is23(46%),left side is 18(36%) and bilateral involvement is 9(18%).

DURATION OF SYMPTOMS:

TABLE 5: DURATION OF SYMPTOMS

Group	*N*	Minimum duration	Maximum duration	Mean duration	Standard deviation
1.Botulinum	*50*	*3*	*20*	*6.8*	4.02
2.Steroid	*50*	*3*	*20*	*7.3*	4.23

CHART 7 - DURATION OF SYMPTOMS



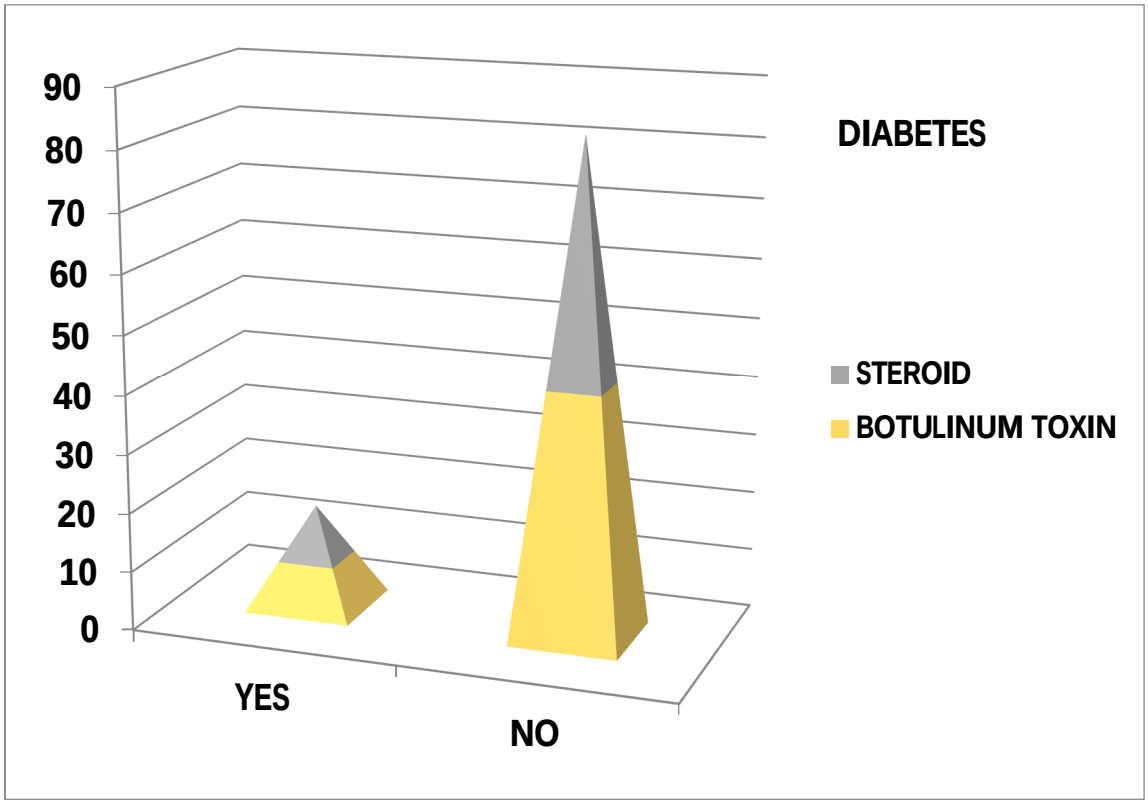
Most of the participants in group 1 and 2 had symptom duration about 3- 6 months**.** The mean duration in group1 is about 6.8 months and in group 2 is about 7.3 months.

COMORBID ILLNESS-DIABETES:

TABLE 6:FREQUENCY OF DIABETES IN STUDY GROUP

Group	N	Diabetes	Frequency	Percent
1.Botulinum Toxin B	50	YES	8	16
		NO	42	84
2.Steroid	50	YES	9	18
		NO	41	82

CHART 8



In the study group 1 there was 8 diabetes and 9 in group 2.Peripheral neuropathy ruled out and all are under diabetic control with medications.

TREATMENT GROUPS-DISEASE DEMOGRAPHY-I

TABLE 7:DISEASE DEMOGRAPHY-I

Features		Treatment group				Chi square test p value
		1.Botulinum		2.Steroid		
		Freq	%	Freq	%	
H/O Early morning pain	Y	49	98	48	96	0.343
	N	1	2	2	4	
H/O Night pain	Y	4	8	6	12	0.444
	N	46	92	44	88	
Deformity	Y	12	24	11	22	0.812
	N	38	76	39	72	
OA knee	Y	8	16	6	12	0.564
	N	42	84	44	88	
Windlass test	positive	47	94	46	92	0.695
	Negative	3	6	4	8	
Medial heel pain	Y	44	88	42	84	0.564
	N	6	12	8	16	

In this study ,in group 1 ,49(98%) and in group 2 ,48(96%) had H/O early morning heel pain. In both study groups there is only 4 to 6 participants having night pain.

12 participants in group1and 11 participants in group 2 has deformity like pes planus and pes cavus.

Windlass test is positive in 47 participants(94%) in group 1 and in 46(92%)participants in group 2.

Nearly 84-86% of the participants had medial heel pain.

DISEASE DEMOGRAPHY –II

TABLE 8- DISEASE DEMOGRAPHY

Findings	N	Frequency	
		Yes	No
Hypertension	100	9	91
Trivial trauma		5	95
Night pain		7	93
Ankle DF ROM		3	97
Leg length discrepancy		0	100
Gait difficulty		10	90
Spine -spondylosis		3	97

- Foot wear abnormalities not assessed in this study.
- Only three participants had restricted ankle dorsiflexion.
- Ten participants had severe antalgic gait.
- No leg limb discrepancy noted among participants.
- Degenerative changes of spine and knee present in participants also assessed and treated.

STUDY PARAMETERS IN THE GROUPS:

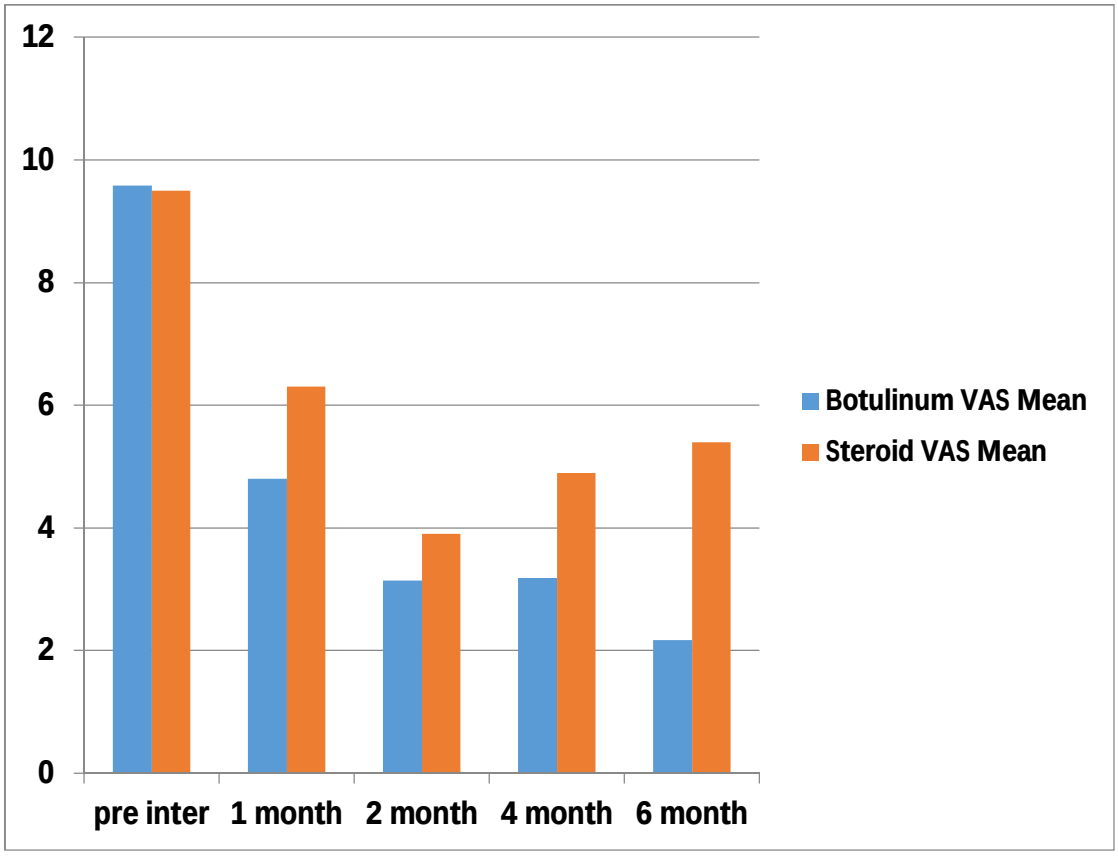
The outcome scale used in our study are visual analogue scale(VAS),Foot Ankle Ability Measure(FAAM).

PAIN-VAS SCORE:

TABLE 9:VAS SCORE

Group	Statistics	PAIN-VAS SCORE				
		Pre inter	**1 month**	**2 month**	**4 month**	**6 month**
1.Botulinum toxin	Mean	9.58	4.8	3.14	3.18	2.74
	S.D	0.702	0.755	0.534	1.043	1.293
	Median	10	5	3	3	3
2.steroid	Mean	9.4	6.3	3.9	4.9	5.4
	S.D	0.788	0.707	0.707	1.326	1.293
	Median	10	6	4	5	5

CHART 9 : VAS SCORE



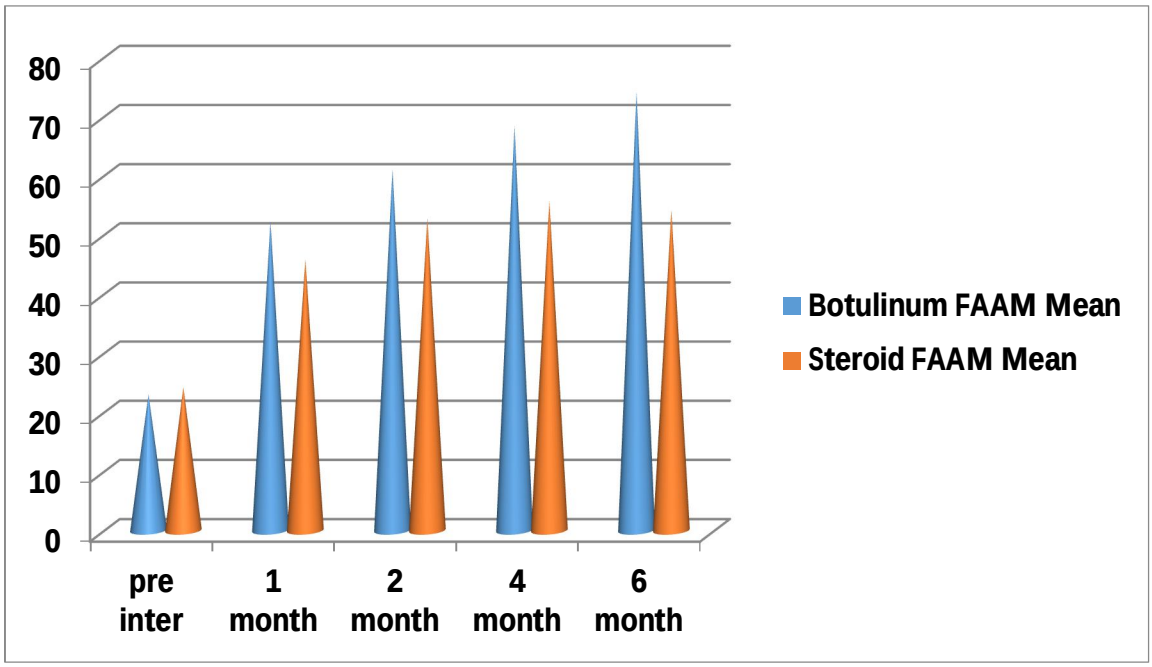
In group 1 ,pre intervention mean VAS score was 9.58 and in group 1 mean VAS was 9.4.post intervention VAS at 1 month and 2 month reduced significantly in both groups .After 4th month and 6th month there is significant reduction and maintenance of VAS score in group1 ie BTX-A compared to group 2

FAAM SCORE:

TABLE 10:FAAM SCORE

Group	Statistics	FAAM SCORE				
		Pre inter	1 month	2 month	4 month	6 month
1.Botulinum toxin	Mean	23	52.26	61.12	68.46	74.18
	S.D	4.261	5.783	5.762	6.581	4.148
	Median	22.5	46	60	69	74
2.steroid	Mean	24.22	45.84	52.8	55.78	54.18
	S.D	4.925	6.931	6.931	5.334	4.493
	Median	23	54	54	57	55

CHART 10



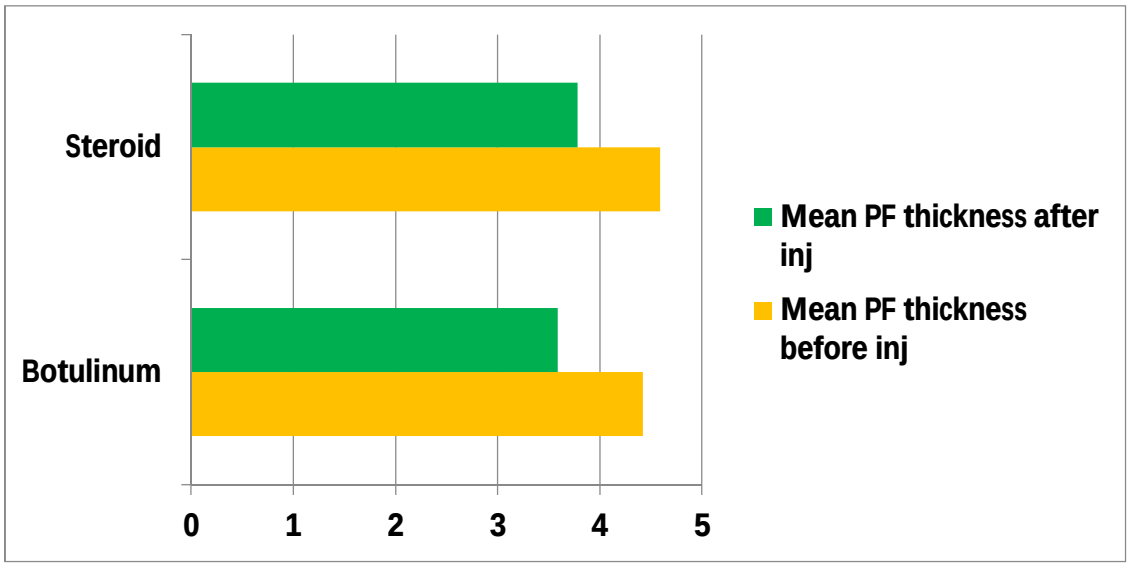
In group 1, the preintervention mean FAAM score was 23 out of 100 and in group 2 ,the preintervention mean FAAM score was 24.22.Post intervention FAAM score in group 1 at 6 month was 74.18 and in group 2 it was 54.18.

PLANTAR FASCIA THICKNESS BY USG:

TABLE 11:PLANTAR FASCIA THICKNESS

Group	Statistics	PF thickness by USG in mm	
		Pre intervention	Post intervention (6 months)
1.Botulinum toxin	Mean	4.42	3.59
	S.D	0.586	0.384
	Median	4.4	3.7
2.steroid	Mean	4.59	3.78
	S.D	0.493	0.347
	Median	4.6	3.8

CHART 11 - PF THICKNESS IN MM



Before intervention, plantar fascia thickness was assessed by USG and mean PF thickness found to be 4.42mm in group 1 and 4.59 in group 2.Post intervention mean PF thickness at 6 months in group 1 was 3.59 and in group 2 was 3.78.

TABLE 12

PRE AND POST INTERVENTION DATA ANALYSIS

Measures	**statistics**	**Group1**		**Group2**	
		Pre inter	**Post inter**	**Pre inter**	**Post inter**
VAS	M	9.58	2.74	9.4	5.4
	SD	0.702	1.293	0.788	1.293
FAAM	M	23	74.18	24.22	54.18
	SD	4.261	4.148	4.925	4.493
PF Thickness	M	4.42	3.59	4.59	3.78
	SD	0.586	0.384	0.493	0.347

TABLE 13

INTRA GROUP COMPARISON-STATISTICAL ANALYSIS

Study group	Paired t test p value			
	1 month	**2 month**	**4 month**	**6 month**
Group 1	<0.00001	<0.0001	<0.0001	<0.0001
Group 2	<0.0001	<0.001	<0.001	<0.001

TABLE 14

INTERGROUP COMPARISON-STATISTICAL ANALYSIS

Group	Unpaired t test			
	1month	**2 month**	**4 month**	**6 month**
1 vs 2	<0.001	<0.001	<0.001	<0.001

Discussion

DISCUSSION

In an average 3-5 cases per day of PF are attending PMR opd in our Government Institute Of Rehabilitation Medicine hospital. In this study 100 participants were included with 50 participants in each group(Group1:Group2) selected by randomized controlled trials.

Mostly the participants belong to low and moderate socio economic status and are doing semiskilled works including house wives which correlates with previous studies by Gill and Kiebzak which says that those who continuously stand or walk, doing weight bearing activities, house hold works are more prone to develop PF[59].

Most of the participants were between 31 to 40 yrs and between 41 to 50 yrs in our study. The mean age years affected by PF is 44.6 yrs in group 1 and 44.8 yrs in group 2 which is also correlated with studies of Jamal et al which says PF is more common in middle aged persons at mean age of 48.6 yrs[34.]

In group 1 there was 19 males(38 %) and 31 females(62%).In group 2 there was 18 males(36%) and 32 females(64%). Females are involved more than males in both groups in our study,but still there is no clear evidence in previous studies whether it is more common in males or females.Catherine et al in their study showed that Females more than 50 yrs of age is commonly affected which correlates with our study[60].

Risk factors like BMI,deformity of foot also included in this study Body mass index results of this study proves that overweight and obesity is one of the risk factor of PF which correlates with study shown by Klein et al[18].

Only 10-20 percent had pes planus and pes cavus deformity in our study and is not as significant went compared to previous study by sahin et al where high arch foot has been significant risk factor for plantar fasciitis[61].

Most of them had early morning heel pain and pain aggravation during prolonged standing and mainly antero medial heel pain over calcaneal tuberosity. very few of them has arch pain also.

In our study laterality of involvement is more or less equal with slight increase in involvement of right sided plantar fasciitis which is not comparable to previous study by Ahmad et al which shows left side plantar fasciitis is common[34].

In this study ,most patient has symptom period of 3- 6 months and the mean duration is 6-7 months.

The comorbid illness associated with the participants is mainly diabetes is about 16-18% and hypertension in only 5 cases. In our study 12-16% has osteoarthritis and 10% has lumbar spondylotic changes.

The ankle dorsiflexion is restricted in only 3 cases which is not as significant in previous study of Patel A et al which shows restricted ankle dorsiflexion as one of the risk factor for plantar fasciitis[62].

There was no limb length discrepancy noted in the participant in this study and foot wear biomechanics are not analysed in this study.

Parameters and scales in both group were analysed by chi square test, paired t test within group and unpaired t test between two groups.VAS score and FAAM score values was statistically significant with p value>0.00001 in group 1 after 1 month of post intervention and with p value>0.0001 maintained at 6 months after intervention. Whereas in group 2 it was >0.0001 at 1month and >0.001 at 6 months after intervention.

The mean VAS score was 2.7 and mean FAAM score was 74.18 in group1 and this results were comparable with previous study by Ahmad et al where mean VAS score was 3.6 and mean FAAM score was 73.8 after Botulinum at 6 months[34].

Both groups shows significant reduction in pain and functional outcome upto 12-14 weeks of intervention with more significant results in group within 4 weeks but after 16 weeks group1 BTX-A shows reduction and maintainence of VAS score and improvement in function proved by increase in FAAM score. In group 2 the VAS score shows no significant decrease in pain level and functional activity also reduced as shown by less FAAM score.

The PF fascia thickness is significantly reduced in BTX-A group compared to steroid group after 6 month of intervention. The mean plantar fascia thickness after Botulinum at 6 months was 3.59 which was comparable to study done by Y-C Huang et al[6].But correlation between PF thickness and VAS score is not done in this study.

Complications like mild numbness of foot is noted in two participants in group2 and one in group 1 and heel pad thickness reduced in three participants in group 2 noted by USG when compared to other side. No plantar fascia rupture noted in both groups .

No allergic reactions were noted during intervention. Only 3 three patients in group1 (Botulinum Toxin-A) and seven patients in group2 has no significant improvement in VAS and FAAM score.

Conclusion

CONCLUSION

Plantar fasciitis sometimes leads to unbearable pain and functional limitation in many cases even after conservative or surgical management .This study shows that in Botulinum toxin group there was significant reduction in VAS pain score soon after intervention and it was maintained at 6 months.

There was also improvement in functional level in Botulinum toxin group measured by FAAM score which is maintained after 6 months.

In steroid group there was significant reduction in VAS pain score and FAAM score upto 12-14 weeks but that was not maintained after 16 weeks.

As no adverse reaction was noted in Botulinum group and it is cost effective in reducing pain in Plantar fasciitis within short period after intervention, it can be considered as one of the therapeutic intervention in patient with chronic plantar fasciitis for excellent pain relief whom other conservative management fails or before proceeding to surgical option.

Limitations of the study

LIMITATIONS OF THE STUDY

- Large sample is needed.
- Botulinum toxin injection is costly.
- No long term follow up done in this study.
- Outcomes based on Subjective assessment only.
- Double blinded control study not done.
- Both groups received exercise therapy in addition so effects of intervention alone not possible in this study.
- No control group with placebo included but compared with standard management available for PF.
- There is yet no standard guidelines regarding dosage for Botulinum,in this study dosage guidelines are taken from previous study .

Future scope of the study

SCOPE OF FUTURE STUDY

- Ultrasound guided injections needed for better outcomes.
- Botulinum Toxin-A should be tried for all musculoskeletal pain related conditions.
- Further study regarding high dosage of BTX intervention is needed.
- Research should be done to find the factor that leads to functional disability in plantar fasciitis and that domain is taken into consideration and treated along with intervention.
- Comparative study between effects of steroid, Botulinum and platelet rich plasma therapy in plantar fasciitis are needed.
- Stem cell therapy for plantar fasciitis should be studied in future

Summary

SUMMARY

Plantar fasciitis is one of the most common cause among heel pain disorder seen in OPD in all countries and usually occurs in most individuals in their life time. Even though it is self limiting disorder, if pain didn't relieve by conservative medical and physical modalities, chronic pain will lead to significant morbidity. Surgical management has some disadvantage and also will lead to some emotional disturbances.so simple interventions should be tried to give better pain relief without much complications.

The present study was done to find efficacy of Botolinum Toxin-A versus the standard treatment (steroid) in reducing pain and improving functional outcome in plantar fasciitis.

This randomized control trial study was done for 9 months on 100 participants with Plantar fasciitis from December 2017 to September 2018 in the Department of Physical Medicine and Rehabilitation, K K Nagar, Chennai. Participants were divided into group (Botulinum Toxin-A) and group 2(Steroid) with 50 participants in each group.

In this study most of the participants are females and the ratio of females and males are 3:2 in both groups (p value-0.96). The mean age of participants in both group is 44-46years (p value-0.83).

The pre-intervention scores of both groups like VAS ,FAAM and thickness of fascia were not statistically significant.

The mean VAS and FAAM score in group 1 is statistically more significant at 1 month (p=0.00001), 2 month (p=0.0001), 4 month (p=0.0001) and at 6 month (p=0.001) when compared to group 2.

In group 2,the VAS and FAAM score are statistically significant(p=0.001) but scores are not maintained after 12-14 weeks. The thickness of plantar fascia by USG shows better reduction in group 1 when compared to group 2 and p value is <0.001

Complications like heel pad atrophy noted in three participants when comparing to opposite side in group 2 and one participant in group 1 and 2 in group developed mild numbness of toes. Plantar fascia rupture was not noted in both groups.

Based on the above findings of this study it may be concluded that Botulinum toxin A are safe, cost effective, maintain pain relief for more duration than steroid, with less complications and can be considered as alternative to those with conservative management failure and surgery or any other intervention.

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Annexures

INSTITUTIONAL ETHICS COMMITTEE
MADRAS MEDICAL COLLEGE, CHENNAI 600 003

EC Reg.No.ECR/270/Inst./TN/2013
Telephone No.044 25305301
Fax: 011 25363970

CERTIFICATE OF APPROVAL

To
Dr.T.Geetha
First Year Post Graduate in MD PMR
GIRM, KK Nagar
Chennai

Dear Dr.T.Geetha,

The Institutional Ethics Committee has considered your request and approved your study titled **" THE EFFICACY OF BOTULINUM TOXIN – A VERSUS METHUL PREDNISOLONE ACETATE INJECTION IN REDUCING PAIN AND IMPROVING FUNCTIONAL OUTCOME IN PLANTAR FASCITIS" - NO.11122017**

The following members of Ethics Committee were present in the meeting hold on **05.12.2017** conducted at Madras Medical College, Chennai 3

1. Prof.P.V.Jayashankar :Chairperson
2. Prof.R.Narayana Babu,MD.,DCH., Dean,MMC,Ch-3 : Deputy Chairperson
3. Prof.Sudha Seshayyan,MD., Vice Principal,MMC,Ch-3 : Member Secretary
4. Prof.N.Gopalakrishnan,MD,Director,Inst.of Nephrology,MMC,Ch : Member
5. Prof.S.Mayilvahanan,MD,Director,Inst. of Int.Med,MMC, Ch-3 : Member
6. Prof.A.Pandiya Raj,Director, Inst. of Gen.Surgery,MMC : Member
7. Prof.Shanthy Gunasingh, Director, Inst.of Social Obstetrics,KGH : Member
8. Prof.Rema Chandramohan,Prof.of Paediatrics,ICH,Chennai : Member
9. Prof. Susila, Director, Inst. of Pharmacology,MMC,Ch-3 : Member
10. Prof.K.Ramadevi,MD., Director, Inst. of Bio-Chemistry,MMC,Ch-3 : Member
11. Prof.Bharathi Vidya Jayanthi,Director, Inst. of Pathology,MMC,Ch-3: Member
12. Thiru S.Govindasamy, BA.,BL,High Court,Chennai : Lawyer
13. Tmt.Arnold Saulina, MA.,MSW., :Social Scientist
14. Thiru K.Ranjith, Ch- 91 : Lay Person

We approve the proposal to be conducted in its presented form.

The Institutional Ethics Committee expects to be informed about the progress of the study and SAE occurring in the course of the study, any changes in the protocol and patients information/informed consent and asks to be provided a copy of the final report.

Member Secretary – Ethics Committee

ஆய்வில் பங்கேற்பாளரின் ஒப்புதல் படிவம்

ஆய்வு செய்யப்படும் தலைப்பு:

உள்ளங்கால் திசுபடல சுழற்சி நோய்க்கு உள் ஊசி மருந்து போடுலினம் டாக்ஸின் ஏ மற்றும் மீத்தைல் ப்ரட்னிசலோன் அசிடேட் மூலம் வலி நிவாரணம் மற்றும் செயல்பாட்டு விளைவு பார்த்தல்

ஆய்வாளர் பெயர்: மரு. த. கீதா

ஆய்வு நடக்கும் இடம்: இயற்பியல் மற்றும் புனர்வாழ்வு மருத்துவ துறை, அரசு புனர்வாழ்வு மருத்துவ நிலையம், சென்னை மருத்துவக் கல்லூரி, சென்னை–3.

ஆய்வில் பங்கு பெறுவரின்	பெயர்	:
	வயது	:
	பாலினம்	: ஆண்/பெண்
	பதிவு எண்.	:
	விலாசம்	:
	கைப்பேசி எண்	:

ஆய்வில் பங்கேற்க ஒப்புதல்

இந்த ஆய்வின் விவரங்களும், அதன் நோக்கமும் எனக்கு முழுமையாகவும், தெளிவாகவும், விளக்கப்பட்டது.

எனது சந்தேகங்களை தெளிவாக கேட்டு அறிந்து நிவர்த்தி செய்து கொண்டேன்.

இந்த ஆய்வில் பங்கேற்பதும், ஆய்விலிருந்து எந்த நேரத்திலும் விலகிக் கொள்வதும் எனது தனிப்பட்ட உரிமை என்பதையும் தெரிந்து கொண்டேன்.

எனது உள்ளங்கால் திசுபடல சுழற்சி நோய்க்கு ஆய்வில் குறிப்பிடப்பட்டுள்ள இரண்டில் ஏதேனும் ஒரு சிகிச்சையை மேற்கொள்ளவும் அதனைத் தொடர்ந்து இயல்முறை பயிற்சி சிகிச்சை மேற்கொள்ளவும் சம்மதிக்கிறேன்.

ஆய்வாளர் / பிற மருத்துவர்கள் / நெறிமுறைக் குழு மற்றும் கட்டுப்பாட்டு அதிகாரிகள் / ஆய்வின் தணிக்கையாளர்கள் எனது மருத்துவத் தகவல்களை தெரிந்து கொள்ளவும் ஆய்வின் முடிவுகளை வெளியிடவும் அனுமதிக்கிறேன்.

இந்த ஆய்வில் பங்கு கொள்ள யாருடைய நிர்பந்தமுமின்றி என்னுடைய சொந்த விருப்பத்தின் பெயரில் சுயநினைவுடனும் முழுமனதுடனும் சம்மதிக்கிறேன்.

ஆய்வாளர் கையொப்பம்
மரு. த. கீதா

முதுநிலை பட்டதாரி மாணவர்

அரசு புனர்வாழ்வு மருத்துவநிலையம்
கே. கே. நகர், சென்னை– 600 083.
சென்னை மருத்துவக் கல்லூரி,
சென்னை–600 003.

பங்கு பெறுவோரின் கையொப்பம்
பெயர் :

இடம் :

தேதி :

PATIENT CONSENT FORM

Study Detail : **"To determine the efficacy of Botulinum toxin-A versus methyl prednisolone acetate injection in reducing pain and improving functional outcome in Plantar fasciitis"**

Study Centre : Government Institute of Rehabilitation Medicine, Chennai.

Patient's Name :

Patient's Age :

Identification Number :

Patient/Patient's Parents/Guardian may check (√) these boxes

a) I confirm that I have understood the purpose of procedure for the above study. I have the opportunity to ask question and all my questions and doubts have been answered to my complete satisfaction. ❑

b) I understand that my participation in the study is voluntary and that I am free to withdraw at any time without giving reason, without my legal rights being affected. ❑

c) I understand that sponsor of the clinical study, others working on the sponsor's behalf, the ethical committee and the regulatory authorities will not need my permission to look at my health records, both in respect of current study and any further research that may be conducted in relation to it, even if I withdraw from the study I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published, unless as required under the law. I agree not to restrict the use of any data or results that arise from this study. ❑

d) I agree to take part in the above study and to comply with the instructions given during the study and faithfully cooperate with the study team and to immediately inform the study staff if I suffer from any deterioration in my health or wellbeing or any unexpected or unusual symptoms. ❑

e) I here by consent to participate in this study. ❑

f) I hereby give permission to undergo detailed clinical examination, radiographs,blood investigations and surgical procedure as required. ❑

Signature of the investigator Signature/Thumb impression of the patient

ஆய்வில் பங்கேற்பாளருக்கான தகவல் தாள்

ஆய்வு செய்யப்படும் தலைப்பு

உள்ளங்கால் திசுபடல சுழற்சி நோய்க்கு உள் ஊசி மருந்து போடுலினம் டாக்ஸின் ஏ மற்றும் மீத்தைல் ப்ரட்னிசலோன் அசிடேட் மூலம் வலி நிவாரணம் மற்றும் செயல்பாட்டு விளைவு பார்த்தல்

ஆய்வாளர் பெயர்: மரு. த. கீதா

ஆய்வு நடக்கும் இடம் : இயற்பியல் மற்றும் புனர்வாழ்வு மருத்துவ துறை, அரசு புனர்வாழ்வு மருத்துவ நிலையம், சென்னை மருத்துவக் கல்லூரி, சென்னை–3.

ஆய்வில் பங்குபெறுவரின்	பெயர்	:
	வயது	:
	பாலினம்	: ஆண்/பெண்
	பதிவு எண்.	:
	விலாசம்	:
	கைப்பேசி எண்	:

பங்கேற்பாளருக்கான தகவல்

உள்ளங்கால் திசுபடல சுழற்சி நோயில், குதிகாலில் காலையில் எழுந்து நடந்தவுடன் மிகுந்த குதிகால் வலி காணப்படும். இந்த நோய் ஆண், பெண் இருபாலரையும் பாதிக்க கூடியது. வலி நிவாரண மாத்திரைகள், இயல்முறை சிகிச்சை சில நேரத்தில் பயன் அளிக்காது.

திட்டமிடப்பட்டுள்ள ஆய்வின் நோக்கம்:

உள்ளங்கால் திசுபடல சுழற்சி நோய்க்கு உள் ஊசி மருந்து போடுலினம் டாக்ஸின் ஏ மற்றும் மீத்தைல் ப்ரட்னிசலோன் அசிடேட் மூலம் வலி நிவாரணம் மற்றும் செயல்பாட்டு விளைவு பார்த்தல்.

ஆய்வு நடைமுறைகள்

பங்கேற்பாளரின் ஒப்புதலுக்குப் பிறகு ஒரு பிரிவினர்களுக்கு ஐம்பது யூனிட் போடுலினம் டாக்ஸின் ஏ ஊசி மருந்து பாதத்தில் இரண்டு இடங்களில் கொடுக்கப்படும். மறுபிரிவினருக்கு மீத்தைல் ப்ரட்னிசலோன் அசிடேட் பாதத்தில் போடப்படும். அதனை தொடர்ந்து இயல்முறை பயிற்சி சிசிச்சையும் அளிக்கப்படும். பின்னர் குறிப்பிட்ட மாதங்களில் வலி நிவாரணம் குறித்து ஆய்வு செய்யப்படும்.

பதிவேடுகளின் ரகசியத் தன்மை:

உங்கள் மருத்துவப் பதிவேடுகள் மிகவும் ரசியமாக வைத்துக் கொள்ளப்படும். அதேசமயம் இந்த ஆய்வில் உங்களது மருத்துவத் தகவல்களை மற்ற ஆய்வாளர்கள் / பிற மருத்துவர்கள் / விஞ்ஞானிகள் / நெறிமுறைக்குழு மற்றும் கட்டுப்பாட்டு அதிகாரிகள் / ஆய்வுத் தணிக்கையாளர்கள் ஆகியோர் படித்து தெரிந்து கொள்ள அனுமதிக்கப்படலாம். ஆய்வின் முடிவுகள் பிரசுரிக்கப்படலாம். ஆனால் எக்காரணம் கொண்டும் உங்கள் தனிப்பட்ட அடையாளம் வெளியிடப்படமாட்டாது.

ஆய்வில் பங்கேற்பாளரின் பொறுப்புகள்:

உங்களுக்கு சிகிச்சை அளிக்கும் / ஆய்வு செய்யும் மருத்துவருடன் முறையான சிகிச்சை மற்றும் பயிற்சிக்காக முழுமையாக ஒத்துழைக்குமாறு கேட்டுக் கொள்ளப்படுகிறீர்கள். . மருத்துவரின் அறிவுரைகளை முறையாக பின்பற்றுமாறும், செய்யக் கூடியன/ கூடாதவற்றை தெளிவாக கேட்டு அறிந்து பின்பற்றுமாறும் கேட்டுக் கொள்ளப்படுகிறார்கள்.

ஆய்வில் உங்கள் பங்கேற்பு மற்றும் உங்கள் உரிமைகள்:

இந்த ஆய்வில் உங்கள் பங்கேற்பு தன்னிச்சையானது மற்றும் காரணம் எதையும் கூறாமலேயே நீங்கள் எந்த ஒரு நேரத்திலும் இந்த ஆய்விலிருந்து விலகிக் கொள்ளலாம். நீங்கள் ஆய்வில் பங்கேற்றாலும், பங்கேற்காவிட்டாலும் உங்கள் உடல்நிலைக்கு ஏற்ப உங்கள் நோக்கு தகுந்த சிகிச்சை அளிக்கப்படும். நீங்கள் ஆய்வில் பங்கேற்க மறுத்தால் நோய்க்கான சிகிச்சைக்கோ அல்லது அடுத்து வரும் நேரத்திலும் நீங்கள் மோசமாக உணர்ந்தாலோ அல்லது உடல்நலக் குறைவு உண்டானாலோ உடனடியாக மருத்தவரைத் தொடர்பு கொள்ளலாம். சிகிச்சை உங்களுக்குப் பொருத்தமானதாக இருக்காது என்றுனு தோன்றினால் உடனடியாக நிறுத்தப்படும். உங்கள் சம்மதம் இன்றியே கூட ஆய்வு நிறுத்தப்படுவது சாத்தியமே. வேறு ஏதேனும் கேள்விகள் / பிரச்சினைகள் பற்றி நீங்கள் கேட்க விரும்பினால், ஆய்வாளரைத் தொடர்பு கெள்ளவும்.

ஆய்வாளர் கையொப்பம்

மரு. த. கீதா

முதுநிலை பட்டதாரி மாணவர்

அரசு புனர்வாழ்வு மருத்துவ நிலையம்,
கே. கே. நகர், சென்னை–600 083.
சென்னை மருத்தவக் கல்லூரி
சென்னை–600 003.

பங்குபெறுபவரின் கையொப்பம்

(மருத்துவரால் படித்துக்காட்டப்பட்டது.

பெயர்:

இடம்:

தேதி:

PATIENT INFORMATION SHEET

A study titled “To determine the efficacy of Botulinum toxin-A versus Methyl Prednisolone Acetate injection in reducing pain and improving functional outcome in Plantar fasciitis" is being conducted at Government Institute of Rehabilitation Medicine, K K Nagar, Chennai 600083.

The purpose of this study is to compare the pain relief and functional outcome among thetwo treatment groups of patients with Plantar fasciitis. Patients with above said condition will be treated with either 50 units of Botulinum toxin-A or 40 mg of Methyl prednisolone acetate injection, followed by scheduled exercise therapy and pain relief is assessed using pain scales.The privacy of the patients in the research will be maintained throughout the study. In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared.

Taking part in this study is voluntary. You are free to decide whether to participate in this study or to withdraw at any time; your decision will not result in any loss of benefits to which you are otherwise entitled.

The results of the special study may be intimated to you at the end of the study period or during the study if anything is found abnormal which may aid in the management or treatment.

Signature of investigator Signature of participant

Place: Chennai

Date :

PROFORMA

Name: Age/sex:

Occupation: op number:

Study registration No:

Address :

Contact number:

Height : weight: BMI:

BP: mmHg

If any:known case of Diabetes/Hypertension/malignancy/heart disease/Tuberculosis

CHIEF COMPLAINTS:

1)- Pain:site

Duration :

Location:

Character:

Radiation :

Aggravating factors:

Relieving factors:

Night pain:Yes/No

Early morning pain:Yes/No

2. congenital deformity of foot:Yes/No

3. H/O Trauma:Yes/No

4. H/O surgery:Yes/No

5.H/O any systemic illness:Yes/No

6.H/O previous treatment:Yes/No

7.Family H/O:

GENERAL EXAMINATION:

Anaemic/jaundice/cyanosis/sweating/pedal oedema/generalised lymphadenopathy

Temp: pulse: BP: Resp rate:

SYSTEMIC EXAMINATION:

CVS: **RS:** **CNS:**

LOCAL EXAMINATION:

Inspection:

- Attitude:
- Alignment of foot and toes:
- Nail beds,web space:
- Any wasting:
- Any callosities/corn/trophic ulcer:
- Shape and size of heel/prominence of heel:
- Alignment and continuity of tendoachilles:
- Any deformity foot:
- Medial longitudinal arch:

PALPATION:

- Localised warmth:
- swelling:
- Abnormal mobility:
- Bony Tenderness:
- Palpate the medial longitudinal arch:
- Palpation of peripheral pulses:

POWER:

- Ankle dorsiflexion/plantar flexion:

SENSATION:

RANGE OF MOVEMENTS:

- Ankle dorsiflexion/plantar flexion:
- Inversion/eversion:
- Abduction/adduction of forefoot:
- Windlass test:
- Jack test:
- Varus/valgus stress test:

MEASUREMENTS:

- Leg length discrepancy:
- Equinus deformity/calcaneal deformity:

FOOT WEAR EXAMINATION:

- Distortion of foot wear:
- Wrinkling of foot wear:
- Bulging out and thinning of vamp:
- Deformation of sole/borders of sole:

GAIT EXAMINATION:

EXAMINATION OF KNEE/HIP/SPINE:

PROVISIONAL DIAGNOSIS:

SCALES:

1. Visual analogue scale:
2. FAAM SCORE(Foot ankle ability measure):

INVESTIGATIONS:

1. Fasting and post prandial blood sugar:
2. X-ray ankle with foot-AP and lateral view:
3. Ultrasonagram Sole:Thickness of plantar fascia:

PROPOSED TREATMENT:

- Group 1 will receive Injection Botulinum Toxin A 50 Units injected into medial tender region near calcaneal tuberosity.
- Group 2 will receive injection methyl prednisolone acetate 40mg into medial tender point near calcaneal tuberosity.
- Both will receive scheduled Exercise Therapy.

SCALES	**DAY 0**	**After 1 month**	**After 2 months**	**After 4 months**	**After 6 months**
Visual Analogue scale					
FAAM SCORE(Foot ankle ability measure)					
Thickness of plantar fascia by ultrasonagram		–	–	–	

KEY TO MASTER CHART

Random Number:

1-50 units of Botulinum toxin-A injection.

2-40 mg of methyl prednisolone acetate with 1ml of 2% lignocaine.

Age:

1-20 to 30 yrs,2-31to 40yrs,3-41to 50 yrs,4-51 to 60 yrs.

Sex :

1-Male,2-Female.

Occupation:

1-No job,2-Manual labour,3-House wife, 4-Non Professional,5-Professional.

BMI:

1-Underweight,2-Normal,3-Overweight,4-Obese.

Diabetes:

1-yes,2-no.

Heel Pain:

1-Medial heel pain.2- Plantar heel pain.

Side:

1-Right,2-left,3-Bilateral

Duration Of Symptoms:

1)3-6 MONTHS,2)6-12MONTHS,3)12-24 MONTHS

Early Morning Pain& Trivial Trauma

1-yes,2-No.

Deformity :

1-pes planus,2-pes cavus,3-No.

Night Pain& Ankle Rom

1-yes,2-no.

Night Pain:

1-yes,2-no.

Leg Length Discrepancy:

1-yes,2-no.

Examination of hip/knee/LS Spine:

1-yes,2-no

X-Ray Lateral Ankle:

1-calcaneal spur,2-No.

USG Plantar Fascia Thickness:

1)2-3mm,2)3.1-4mm,3)4.1-5mm,4)>5.1mm

Complications:

1)Heel Pad Atrophy,2)Numbness Of Foot,3) No

MASTER CHART

SL NO	OP NO	RANDOM NUMBER	AGE	SEX	OCCUPAT	BMI	DM	HEEL PAIN	SIDE	DURATION	EARLY MORNING PAIN	TRAUMA	DEFORMITY	NIGHT PAIN	ANKLE ROM	WINDLASS TEST	LEG LENGTH	GAIT	HIP	KNEE	SPINE	X-RAY	PRE VAS	VAS @ 1 MONTH	VAS @ 2 MONTH	VAS @ 4 MONTH	VAS @ 6 MONTH	PRE FAAM	FAAM @ 1 MONTH	FAAM @ 2 MONTH	FAAM @ 4 MONTH	FAAM @ 6 MONTH	PRE USG	USG 6 MONTH	COMPLICATION
1	11190	1	4	1	1	2	2	1	2	1	1	2	2	2	1	1	1	1	1	2	1	2	10	6	3	3	3	34.00	54	58	64	72	4.8	3.98	3
2	432	2	2	2	2	2	2	1	1	1	1	2	1	1	2	1	1	1	1	1	1	2	9	7	4	4	5	28	45	45	51	55	4.4	4.01	3
3	869	1	3	2	4	3	2	1	1	3	1	2	3	2	1	1	1	1	1	1	1	2	10	5	3	4	3	18	50	68	58	59	4.8	3.89	3
4	3448	2	3	2	2	3	2	1	3	1	1	2	3	1	1	1	1	1	1	1	1	1	10	6	3	4	5	24	47	56	52	52	5.4	4.1	3
5	454	1	2	2	3	4	2	1	2	1	1	2	3	2	1	1	1	1	1	1	2	1	10	5	3	2	2	22	56	64	76	78	4.13	3.87	3
6	4396	2	2	1	1	2	1	1	1	3	1	2	1	2	1	1	1	1	1	1	1	1	8	7	4	5	5	19	48	63	60	61	5.12	4.2	3
7	281	1	4	2	3	3	2	2	1	2	1	1	3	2	1	1	1	1	1	2	1	1	10	4	3	3	3	23	44	64	69	76	3.82	3.8	3
8	5029	2	2	2	3	2	2	1	3	1	1	2	3	2	1	2	1	1	1	1	1	1	10	5	5	4	4	21	49	58	58	57	4.76	3.96	3
9	429	1	3	2	3	3	2	1	2	2	1	2	1	2	1	1	1	1	1	1	1	1	9	6	3	3	3	24	54	63	68	72	4.93	4.01	3
10	5407	2	4	1	2	2	2	1	1	1	1	1	3	2	1	1	1	1	1	1	1	2	10	7	5	4	4	26	42	56	58	54	4.98	3.98	3
11	2359	1	2	1	2	3	1	1	3	3	1	2	3	2	1	1	1	2	1	1	1	1	9	5	2	4	3	18	54	65	76	76	5.31	4.02	3
12	3194	2	2	2	3	2	2	2	2	1	2	2	2	2	1	1	1	1	1	1	1	1	10	6	4	3	5	27	34	54	56	54	5.6	3.87	2
13	2840	1	2	1	5	4	2	1	2	3	1	2	3	2	1	1	1	1	1	1	1	2	10	5	3	2	3	24	58	69	78	80	5.75	3.45	3
14	5407	2	4	1	2	2	1	1	1	1	1	2	3	2	1	1	1	1	1	1	1	2	9	6	4	3	4	16	48	64	62	59	4.8	4.1	3
15	2411	1	3	2	3	3	2	1	1	1	1	2	3	2	2	1	1	1	1	1	2	2	10	6	2	4	3	17	55	68	60	60	4.1	3.65	3
16	3240	2	3	2	3	4	1	1	1	3	1	2	1	2	2	1	1	1	1	1	1	1	8	5	4	6	7	23	46	64	61	59	4.89	3.9	3
17	4328	1	2	2	3	3	2	1	3	3	1	2	3	2	1	1	1	1	1	1	1	1	10	6	3	4	3	21	54	70	80	80	5.75	3.78	3
18	5123	2	4	2	3	3	1	1	2	2	1	2	3	1	1	1	1	1	1	1	1	1	7	5	3	4	5	19	46	54	59	61	4.65	3.86	3
19	1680	1	3	2	3	2	2	1	2	1	1	2	3	1	1	1	1	1	1	1	1	2	10	5	3	4	2	24	52	66	79	79	2.8	2.89	3
20	3452	2	3	2	3	3	1	2	2	1	1	2	3	2	1	1	1	2	1	1	1	1	10	7	4	3	6	28	48	54	58	56	4.78	3.75	3
21	11280	1	4	1	1	2	2	2	2	1	1	2	3	2	1	2	1	1	1	2	2	1	10	6	3	2	1	32	58	62	72	76	4.65	3.84	3
22	2140	2	3	2	3	3	2	1	3	3	1	2	1	2	1	1	1	1	1	2	1	2	10	7	2	4	4	18	47	56	54	56	4.2	4.1	3
23	2157	1	2	2	3	2	2	1	1	1	1	2	3	2	1	1	1	1	1	2	1	1	10	5	3	3	3	27	52	68	68	72	4.09	3.12	3
24	8321	2	4	2	3	3	2	2	2	2	1	2	3	1	1	1	1	1	1	1	1	1	10	6	4	4	5	19	49	56	58	55	4.64	3.98	1
25	4518	1	3	2	5	2	2	1	2	2	2	2	3	2	1	1	1	2	1	1	1	1	9	4	3	3	3	24	48	58	70	73	5.03	4.02	3
26	868	2	3	2	2	4	2	2	1	1	1	2	2	2	1	1	1	1	1	1	1	2	10	6	4	5	5	23	46	46	54	53	3.95	3.76	3
27	2462	1	3	2	2	2	1	1	2	1	1	1	1	2	1	2	1	1	1	1	1	2	9	4	3	3	3	19	48	58	74	78	4.43	3.56	3
28	3998	2	3	2	2	3	2	1	3	1	1	2	3	2	1	2	1	1	1	1	1	2	8	7	3	4	5	21	46	60	62	61	4.76	4.08	3
29	2759	1	1	1	2	2	2	1	1	1	1	2	3	2	1	1	1	1	1	1	2	2	10	5	3	4	2	18	54	58	69	71	3.95	3.45	3
30	755	2	2	1	2	3	2	1	1	1	1	2	3	2	1	1	1	1	1	1	1	1	9	6	4	3	4	23	45	54	54	53	5.23	4.68	3
31	471	1	1	1	5	2	2	1	1	1	1	2	3	1	1	1	1	1	1	1	1	1	9	3	3	3	3	19	34	45	48	58	4.52	3.06	3
32	5442	2	3	2	3	3	1	2	2	3	1	2	3	2	1	1	1	1	1	2	1	1	9	6	4	5	5	21	51	65	61	59	4.9	3.8	1
33	7292	1	4	2	1	2	2	1	3	1	1	2	3	2	1	1	1	2	1	2	1	2	10	5	3	4	4	23	54	59	65	71	4.32	3.87	3
34	13734	2	4	2	3	3	2	1	3	2	1	2	3	2	1	1	1	1	1	1	1	1	10	7	3	5	6	19	48	48	56	52	4.45	3.98	3
35	6009	1	2	2	4	4	2	1	1	2	1	2	3	2	1	1	1	1	1	1	1	1	10	5	2	4	3	20	54	60	74	82	4.78	3.56	3
36	5715	2	1	2	4	2	2	1	1	2	1	2	3	2	1	1	1	1	1	1	1	1	10	6	4	4	5	24	58	58	54	50	4.86	3.9	3

SL NO	OP NO	RANDOM NUMBER	AGE	SEX	OCCUPAT	BMI	DM	HEEL PAIN	SIDE	DURATION	EARLY MORNING PAIN	TRAUMA	DEFORMITY	NIGHT PAIN	ANKLE ROM	WINDLASS TEST	LEG LENGTH	GAIT	HIP	KNEE	SPINE	X-RAY	PRE VAS	VAS @ 1 MONTH	VAS @ 2 MONTH	VAS @ 4 MONTH	VAS @ 6 MONTH	PRE FAAM	FAAM @ 1 MONTH	FAAM @ 2 MONTH	FAAM @ 4 MONTH	FAAM @ 6 MONTH	PRE USG	USG 6 MONTH	COMPLICATION
37	4769	1	1	2	3	3	2	1	3	2	1	2	3	2	1	1	1	1	1	1	1	2	9	4	3	3	2	26	46	62	79	79	5.32	3.98	3
38	5110	2	2	2	3	3	2	1	1	2	1	2	3	2	1	1	1	1	1	1	1	2	10	7	4	5	5	32	44	48	58	51	4.65	4.1	3
39	4530	1	4	2	3	3	2	1	2	1	1	2	3	2	1	1	1	1	1	2	1	1	9	5	3	3	3	19	48	68	68	73	4.85	3.71	3
40	8119	2	2	1	4	2	2	1	3	1	1	2	3	2	1	1	1	1	1	1	1	1	10	6	3	3	4	18	54	62	59	50	4.32	3.98	3
41	7288	1	3	2	3	3	2	1	2	1	1	2	1	2	1	2	1	1	1	1	2	2	10	6	3	2	2	21	59	62	65	72	4.05	3.54	3
42	7625	2	2	2	3	2	2	1	1	1	2	2	2	1	1	1	1	1	1	1	1	2	9	6	4	3	4	23	50	54	57	52	4.15	3.82	3
43	7821	1	3	2	3	2	1	1	1	1	1	2	3	1	1	1	1	1	1	1	1	2	8	4	4	2	2	21	48	56	76	80	4.23	3.43	3
44	7844	2	1	2	4	4	2	1	3	2	1	2	3	2	1	1	1	1	1	1	1	1	10	6	4	4	5	23	56	58	63	60	5.1	4.1	3
45	7850	1	2	1	2	2	2	2	2	1	1	2	3	2	1	1	1	2	1	1	1	1	10	3	3	4	3	19	58	58	77	81	4.54	3.98	3
46	6130	2	4	2	3	2	1	1	1	1	1	2	3	2	1	1	1	1	1	1	1	1	10	7	4	3	5	18	55	58	62	59	4.78	3.87	3
47	7972	1	1	2	3	3	2	1	3	1	1	2	2	2	1	1	1	1	1	1	1	1	10	5	3	3	3	20	66	68	68	73	4.34	3.43	3
48	8693	2	3	2	3	2	2	1	2	3	1	2	2	2	1	1	1	1	1	1	2	1	10	6	4	5	6	25	59	64	62	60	4.5	4.1	1
49	8824	1	3	2	3	3	2	1	1	1	1	2	3	2	1	2	1	1	1	1	1	1	10	6	3	3	2	31	60	60	74	78	4.7	3.98	3
50	9116	2	3	2	3	2	2	1	2	2	1	2	3	2	1	1	1	1	1	1	1	1	10	7	4	3	4	21	48	48	53	51	4.94	3.68	3
51	9000	1	2	2	3	2	2	1	1	2	1	2	3	2	1	1	1	1	1	1	1	1	10	5	3	3	3	18	52	69	69	72	4.35	3.98	3
52	9224	2	3	1	2	3	2	1	1	1	1	2	3	2	1	1	1	2	1	1	1	1	10	5	5	7	7	22	39	42	57	51	4.23	3.98	3
53	9200	1	4	1	4	2	1	1	3	2	1	2	3	1	1	1	1	2	1	1	1	1	10	4	3	3	3	18	49	49	68	76	4.55	4.1	3
54	9439	2	4	1	1	2	2	1	1	1	1	2	3	1	1	1	1	1	1	2	1	2	8	6	3	5	3	32	59	62	62	61	4.34	3.89	3
55	9550	1	2	2	4	3	2	2	1	1	1	2	3	2	1	1	1	1	1	1	1	2	8	5	3	3	3	19	59	64	70	73	4.65	3.87	3
56	9653	2	2	2	3	3	2	1	1	3	1	2	2	2	1	2	1	1	1	1	1	1	9	7	4	4	3	17	46	53	58	55	5.21	4.23	3
57	9662	1	3	1	2	2	2	1	2	1	1	2	1	2	1	1	1	1	1	2	1	1	10	4	3	3	2	21	54	58	58	76	4.05	3.08	3
58	9964	2	3	2	3	3	2	1	1	1	1	2	1	2	1	1	1	1	1	1	1	2	10	6	4	5	3	23	52	54	60	68	4.81	3.9	1
59	10096	1	4	2	2	2	2	1	3	2	1	2	2	2	1	1	1	1	1	1	1	2	9	4	3	3	3	28	68	68	71	74	4	3.8	3
60	10906	2	3	2	1	3	2	1	1	1	1	2	3	2	1	1	1	1	1	1	1	2	10	7	3	4	4	32	48	57	65	66	4.47	3.75	2
61	10985	1	3	2	3	2	2	1	1	1	1	2	3	2	1	1	1	1	1	1	1	1	10	5	2	4	3	23	52	56	70	72	4.09	3.9	3
62	11079	2	4	1	1	2	2	1	2	1	1	2	3	2	1	1	1	1	1	2	1	1	10	6	3	4	4	27	43	49	57	52	5.27	3.89	3
63	11573	1	3	1	4	3	2	1	1	1	1	2	3	2	1	1	1	1	1	1	1	1	10	5	3	3	3	19	52	65	74	76	4.4	3.26	3
64	11941	2	4	2	1	2	2	1	2	2	1	2	3	2	1	1	1	1	1	1	1	2	10	7	5	5	6	26	41	59	63	62	4.32	3.65	3
65	12001	1	2	2	3	3	2	2	3	1	1	2	3	2	1	1	1	1	1	1	1	2	10	4	3	3	3	22	38	66	73	74	4.8	3.7	3
66	12241	2	4	1	2	2	2	1	2	1	1	2	1	2	1	1	1	1	1	1	1	2	10	6	4	3	3	32	43	56	58	52	4.4	2.98	3
67	12272	1	4	1	2	2	2	1	1	1	1	2	2	2	1	1	1	1	1	1	1	1	10	5	3	4	3	28	64	71	74	74	4.3	3.9	3
68	4249	2	4	2	2	2	2	1	1	1	1	2	3	2	1	1	1	2	1	1	1	2	10	6	4	7	8	39	47	49	52	52	4.5	3.67	3
69	13703	1	2	2	3	3	2	1	1	1	1	2	3	2	1	1	1	1	1	1	1	2	9	4	3	4	2	24	36	51	67	74	4.15	3.78	3
70	428	2	3	1	3	2	1	1	2	2	1	2	3	2	1	1	1	1	1	1	1	2	10	6	3	4	4	29	43	48	51	56	4.58	3.19	3
71	855	1	2	1	4	2	2	1	3	1	1	2	3	2	1	1	1	2	1	1	1	2	10	5	3	3	2	34	53	58	69	69	4.32	3.58	3
72	2155	2	2	2	3	2	2	1	1	1	1	2	3	2	1	1	1	1	1	1	1	2	9	7	4	2	3	28	39	59	62	62	4.34	3.4	3
73	2470	1	1	2	4	2	2	1	1	2	1	2	3	2	1	1	1	1	1	1	1	1	10	4	4	2	2	25	53	59	71	76	4.77	3.29	3
74	3239	2	2	1	3	2	2	1	2	1	1	2	3	2	1	1	1	1	1	1	1	1	10	8	3	5	5	24	38	44	44	51	4.08	3.77	3

SL NO	OP NO	RANDOM NUMBER	AGE	SEX	OCCUPAT	BMI	DM	HEEL PAIN	SIDE	DURATION	EARLY MORNING PAIN	TRAUMA	DEFORMITY	NIGHT PAIN	ANKLE ROM	WINDLASS TEST	LEG LENGTH	GAIT	HIP	KNEE	SPINE	X-RAY	PRE VAS	VAS @ 1 MONTH	VAS @ 2 MONTH	VAS @ 4 MONTH	VAS @ 6 MONTH	PRE FAAM	FAAM @ 1 MONTH	FAAM @ 2 MONTH	FAAM @ 4 MONTH	FAAM @ 6 MONTH	PRE USG	USG 6 MONTH	COMPLICATION
75	3304	1	4	2	3	2	2	1	2	1	1	2	3	2	1	1	1	1	1	1	1	2	10	6	4	2	2	19	51	56	59	74	4.62	3.81	3
76	3421	2	4	1	2	2	2	1	2	2	1	2	3	2	1	1	1	1	1	1	1	1	10	7	4	4	5	21	38	39	45	45	4.71	3.63	3
77	3524	1	2	2	3	2	1	1	2	1	1	2	3	2	1	2	1	1	1	1	1	1	10	5	3	2	3	28	39	55	56	68	4.4	3.45	3
78	3590	2	3	1	3	2	2	2	3	1	1	2	3	2	1	2	1	1	1	1	1	1	10	7	4	4	4	23	37	41	46	58	4.31	4.1	3
79	4037	1	4	1	4	3	2	1	3	1	1	2	2	2	1	1	1	1	1	1	1	1	10	5	4	4	8	24	54	65	67	74	4.69	3.8	3
80	4055	2	2	2	3	3	2	1	1	2	1	2	3	2	1	1	1	1	1	1	1	2	10	6	5	5	6	22	40	45	48	60	4.36	3.25	3
81	4259	1	4	2	3	3	2	1	1	2	1	2	3	2	1	1	1	1	1	1	1	1	10	4	4	8	1	21	41	55	59	67	4.44	4.12	3
82	109877	2	3	1	3	2	2	1	2	1	1	2	3	2	1	1	1	1	1	1	1	2	9	7	5	7	7	24	39	45	49	52	4.3	3.58	3
83	9964	1	3	2	3	4	2	1	2	1	1	2	3	2	1	1	1	1	1	1	1	2	9	5	3	2	2	23	45	64	68	74	4.65	3.96	3
84	9962	2	4	1	2	2	2	2	2	1	1	2	3	2	1	1	1	1	1	2	1	2	10	6	4	4	5	37	48	52	54	54	5.1	4.01	3
85	11753	1	3	1	4	4	2	1	1	3	1	2	3	2	1	1	1	2	1	1	1	1	10	4	4	3	2	29	56	58	68	68	4.3	3.21	3
86	9544	2	4	2	3	3	2	1	2	2	1	2	2	2	1	1	1	2	1	1	1	2	8	5	4	3	7	23	44	48	57	59	5.8	3.9	3
87	13734	1	3	2	3	2	2	1	2	1	1	2	3	2	1	1	1	1	1	1	1	2	9	5	3	3	2	21	53	58	67	74	4.23	3.11	3
88	8233	2	2	1	3	2	1	1	1	2	1	2	3	2	1	1	1	1	1	1	1	1	8	5	4	5	5	25	46	48	57	49	4.62	3.63	3
89	8234	1	2	1	2	3	1	1	2	1	1	2	3	2	1	1	1	1	1	1	1	1	10	4	4	1	1	23	51	56	67	73	2.35	2.36	3
90	4379	2	4	1	2	2	2	1	1	2	1	2	3	2	1	1	1	1	1	1	1	2	9	6	5	5	5	19	41	45	46	54	3.36	3.24	3
91	2321	1	4	1	2	2	2	1	2	1	1	2	3	2	1	1	1	1	1	2	1	2	10	5	4	3	3	25	53	57	66	75	4.4	3.23	3
92	6009	2	2	2	3	3	2	1	2	2	1	2	3	2	1	1	1	1	1	1	1	1	10	7	5	5	3	21	40	44	47	59	3.86	3.56	3
93	6438	1	3	2	3	3	2	1	2	2	1	2	3	2	1	2	1	1	1	1	1	1	10	5	4	3	2	28	64	69	62	62	3.3	3.23	3
94	6524	2	2	2	4	3	1	1	1	1	1	2	3	2	1	1	1	1	1	1	1	2	10	6	3	7	7	23	43	47	49	58	3.5	3.01	3
95	5812	1	3	1	4	2	1	1	1	1	1	2	2	2	1	1	1	1	1	1	1	1	7	4	3	3	3	22	53	57	58	60	4.56	3.12	3
96	4530	2	4	2	3	2	2	2	2	2	1	2	3	2	1	2	1	1	1	2	1	2	9	7	5	4	4	31	41	45	55	52	3.67	3.1	3
97	4939	1	3	1	4	3	2	1	1	1	1	2	3	2	1	1	1	1	1	1	1	2	8	5	4	3	3	24	55	57	67	69	4.4	2.98	3
98	6317	2	2	2	3	4	2	1	3	1	1	2	3	2	1	1	1	1	1	1	1	2	10	6	3	7	5	22	39	43	49	52	4.56	3.24	3
99	4045	1	2	2	3	4	2	2	1	2	1	2	1	2	1	1	1	1	1	1	1	2	9	5	4	5	5	20	53	58	69	74	4.35	3.22	3
100	5539	2	4	2	3	3	2	1	1	1	1	2	3	2	1	1	1	1	1	1	1	1	10	6	3	8	8	23	47	49	56	59	4.23	3.26	3